BERGER & HIPSKIND LLP
Dorian S. Berger, CA Bar No. 264424
Daniel P. Hipskind, CA Bar No. 266763
1880 Century Park East, Ste. 815
Los Angeles, California 90067
Telephone: 323-886-3430
Facsimile: 323-978-5508
Email: dsb@bergerhipskind.com
Email: dph@bergerhipskind.com

AIDS HEALTHCARE FOUNDATION
Tom Myers, CA Bar No. 176008
Arti L. Bhimani, CA Bar No. 235240
Liza M. Brereton, CA Bar No. 261380
6255 W. Sunset Blvd., 21st Fl.
Los Angeles, California 90028
Telephone: 323-860-5200
Facsimile: 323-467-8450
Email: Tom.Myers@aidshealth.org
Email: Arti.Bhimani@aidshealth.org
Email: Liza.Brereton@aidshealth.org

Attorneys for Plaintiff AIDS Healthcare Foundation, Inc.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

AIDS HEALTHCARE FOUNDATION, INC.,

Plaintiff,

v.

GILEAD SCIENCES, INC.;
JAPAN TOBACCO, INC.;
JANSSEN SCIENCES IRELAND UC; AND
JOHNSON & JOHNSON, INC.,

Defendants

Case No. 16-cv-00443-WHA

PLAINTIFF AIDS HEALTHCARE FOUNDATION INC.'S OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS UNDER RULE 12 FOR LACK OF SUBJECT MATTER JURISDICTION AND FAILURE TO STATE A CLAIM

HEARING
Judge: Hon. William Alsup
Date: June 23, 2016
Time: 8:00 a.m.
Location: Courtroom 8, 19th Floor

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

RULES

STATUTES

FDA MATERIALS

I. INTRODUCTION

As the largest non-profit provider of HIV and AIDS medical care in the United States and as one of the largest purchasers of drugs used to treat HIV and AIDS with over 575,000 patients and clients, Plaintiff AIDS Healthcare Foundation, Inc. ("AIDS Healthcare") brings this suit to stop Gilead Sciences, Inc.'s ("Gilead") illegal business practices currently foreclosing affordable access to important, lifesaving HIV and AIDS therapies.

Gilead, in concert with Japan Tobacco, Inc. ("Japan Tobacco"), Janssen Sciences Ireland UC ("Janssen"), Johnson & Johnson, Inc. ("J&J") (collectively, "Defendants") undertook a monopolistic scheme that tied the sales of Tenofavir Alafenamide Fumarate ("TAF") to the sale of other drug products used in the treatment of HIV and AIDS. Defendants' anticompetitive practices arose in response to the upcoming expiration of Gilead's patents covering Tenofovir Disoproxil Fumarate ("TDF") in 2017, which will lead to generic entry in the TDF market and cut into Gilead's multi-billion dollar profits. TDF has been used by physicians to treat HIV and AIDS for the past 15 years in conjunction with a variety of other drugs in various combinations and dosages to form a variety of highly active antiretroviral therapies ("HAART") tailored for individual patients. Because TAF is as efficacious as TDF, but in significantly smaller dosages, thus making it much safer for patients, TAF is replacing TDF as the backbone of HAART therapies.

Concurrent to its development of TDF, Gilead identified TAF as offering superior benefits to those suffering from HIV/AIDS as compared to TDF. However, instead of promptly developing TAF, and to maximize its profits and extend its monopoly in the field of Tenofovir treatments, Gilead hatched a multipronged anticompetitive and unfair scheme, and in the process Gilead violated federal and state antitrust and unfair competition law.

First, Gilead sought to delay the release of TAF to ensure that TAF exclusivity did not overlap with its TDF monopoly until generic entry in the TDF market was imminent. That is, Gilead: (1) delayed bringing TAF to market until TDF was about to face generic competition, and (2) fraudulently stated publically that it was not pursuing TAF as a treatment for HIV/AIDS while contemporaneously applying for multiple patents on TAF. Gilead's intentional delay in pursuing TAF violates California Business and Professions Code § 17200 ("UCL"), which proscribes any

"unfair" business practices. The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act")[1] attempts to balance the public's need for affordable medicines with the innovator's need to recoup research and development costs. To achieve this balance, the Hatch-Waxman framework provides the makers of new drugs with market exclusivity while making it easier for generic drugs to enter the market once that exclusivity period has expired. Pharmaceutical companies have a reputation for "gam[ing]" the system in an attempt to "restrict competition beyond what the Hatch-Waxman Amendments intended."[2] When a company, such as Gilead, intentionally delays the pursuit of lifesaving drugs for no other purpose than to protect its monopoly over an inferior product used to treat the same condition, it destroys the delicate Hatch-Waxman balance, harms the public interest, and violates California's UCL.

Second, when Gilead finally launched treatments for TAF, after years of calculated delay, Gilead sought to maximize its profits from TAF by using its exclusivity in the separate and distinct market for TAF to force on purchasers and patients only a select few of the several complementary drugs to TAF that can form an effective HAART therapy. As AIDS Healthcare's First Amended Complaint (Dkt. No. 50 ("FAC")) explains, Gilead's actions destroy what would otherwise be a competitive market for the tied drugs. The result is that Gilead and its licensing partners are able to illegally prop up the prices on these complementary drugs. Because Gilead did not have rights to these complementary drugs, it entered into exclusive product licenses with Japan Tobacco and Janssen and agreed to share the revenue with its partners for the licensed drugs Gilead tied to the sale of TAF. Defendants' tying agreement is damaging competition in the market for drugs complementary to TAF in the treatment of HIV and AIDS as part of HAART therapies, and it is also limiting treatment options for physicians wishing to tailor HAART therapies for patients with a variety of specific needs.

---

[1] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271).

[2] Declaration of Dorian Berger ("Berger Decl."), Ex. A at 13 (*Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 3, at 13 (Oct. 2003)). AIDS Healthcare requests the Court take judicial notice of materials that are a matter of public record; these documents provide context to the material proffered by Defendants in their motions to dismiss (*e,g.*, Gilead Br. 4 n.1 (requesting the Court take notice of materials that "are matters of public record and appear on the FDA's website.")).

As pled in AIDS Healthcare's complaint, TAF and the complementary drugs utilized as part of HAART therapies are two distinct product markets. Under the Supreme Court's *Jefferson Parish Hospital District No. 2 v. Hyde*, 466 U.S. 2 (1984), decision, two distinct product markets exist where there is sufficient demand for the purchase of the tied product separate from the tying product. *Id.* at 21-22. Here, the FAC alleges sufficient demand for TAF separately from complementary drugs utilized as part of a HAART therapy. Among various indicia that TAF is a distinct product discussed in the FAC are Gilead's own public statements support the argument that TAF is a distinct product and the fact that Gilead has licensed TAF as a "single agent product" to its licensing partners. Gilead's argument that there is no market for TAF because TAF has not yet been approved by the FDA as a standalone product is wrong. The relevant case law establishes that Gilead's unilateral decision not to approach the FDA and seek approval of a standalone version of TAF does not immunize it from antitrust scrutiny.

There is also distinct demand for the tied drugs (elvitegravir, cobicistat, emtricitabine, and rilpivirine) separate and apart from the sale of TAF. Notably, each of these four compounds are marketed separately as standalone products: Vitekta, Tybost, Emtriva, and Norvir, respectively. Because Gilead has market power in TAF and forces purchasers of TAF to purchase separate, distinct drugs, and because this tying arrangement affects a substantial amount of commerce in the tied drugs, Gilead has violated Section 2 of the Sherman Act, California's UCL, which prohibits unlawful business practices, and Nevada's Unfair Trade Practices Act ("UTP"). And because Gilead, Japan Tobacco, and Janssen reached agreements in restraint of trade to effect Gilead's tying scheme, all Defendants have violated Section 1 of the Sherman Act, California's Cartwright Act, the California UCL, and the Nevada UTP.

Defendants' agreement to only release TAF in combination with other drugs also violates California's UCL as an unfair business practice because Defendants are attempting to "game" FDA's Hatch-Waxman's provisions to fend off generic competition by releasing TAF, which has extremely weak patents, as discussed below, with complementary drugs with comparatively strong patents. The effect of this gamesmanship is that a potential competitor seeking to release a generic version of a TAF product must either file an Abbreviated New Drug Application ("ANDA") on a

combination patent and attempt to invalidate all patents associated with the combination product (not just the TAF patents) or pursue what is known as a 505(b)(2) application for a standalone version of TAF.

Defendants intentionally designed their product release schedule in this manner to hinder potential generic competition in the TAF market. Preparing and filing a 505(b)(2) application requires a potential generic competitor to conduct its own clinical investigations into the effectiveness of TAF as a standalone product to treat HIV/AIDS. A potential competitor is unlikely to invest these resources because TAF's NCE exclusivity period prevents the filing of a 505(b)(2) application until November 2019. Therefore, if Gilead files its own application for a standalone version of TAF prior to November 2019, all the potential resources pursuing clinical investigations on standalone TAF will have been wasted as Gilead would obtain an additional 3-year exclusivity on the standalone version of TAF. Defendants' business practice of shielding TAF's weak patents with the stronger patents of the tied drugs to game the Hatch-Waxman provisions in an effort to extend monopoly profits as long as possible at the expense of patient access to affordable versions of lifesaving HIV and AIDS drugs hurts competition, is detrimental to public health, and violates California's UCL. Because AIDS Healthcare's FAC sufficiently alleges violations of state and federal antitrust and unfair competition law, the Court should deny Defendants' Rule 12(b)(6) motions to dismiss these claims.

Finally, in an effort to extend its monopoly on TAF as long as possible, and well beyond the 5-year New Chemical Entity Exclusivity ("NCE exclusivity") period TAF received from the FDA, Gilead obtained patents relating to TAF that are unquestionably invalid. TAF is an obvious derivative of the underlying compound (Tenofovir), which was first synthesized thirty years ago in the Czech Republic. Because AIDS Healthcare is taking significant steps towards bringing generic versions of TAF to market, it seeks a declaratory judgment that the patents covering TAF are invalid. A declaratory judgment action is necessary to avoid undue delay in the marketing of an important new drug. Consistent with the very purpose of the Declaratory Judgment Act, AIDS Healthcare is seeking a declaration that five of Gilead's patents are invalid and, thus, cannot be used to block generic competition.

Gilead argues that AIDS Healthcare's suit fails to present a justiciable controversy. This argument is baseless. Under *MedImmune, Inc. v. Genentech, Inc.*, the facts alleged here "under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 549 U.S. 118, 127 (2007). There is plainly a controversy.

Evidence of the controversy includes: (1) a history of litigation and disputes between AIDS Healthcare and Gilead (FAC ¶ 32); (2) AIDS Healthcare's written requests to generic makers for unlicensed TAF and combination drugs containing TAF (*id.* ¶ 33); (3) Gilead's history of enforcement actions against generic makers entering the Tenofovir field (*id.* ¶ 45); (4) AIDS Healthcare's notice to Gilead that it intends to manufacture and/or import unlicensed TAF and compounds containing TAF (*id.* ¶ 36); (5) Gilead's refusal to provide a covenant not to sue AIDS Healthcare relating to claims of indirect and/or direct infringement of Gilead's TAF patents (*id.* ¶ 35); (6) AISD Healthcare's ongoing inducement of infringement of the TAF patents through public statements soliciting unlicensed entry (*id.* ¶ 34); and (7) Gilead's public statements that it will enforce its patent rights to maintain monopoly control of the market for TAF (*id.* ¶ 44).

There can be no question, based on undisputed facts, that Gilead will attempt to enforce its patents against potential direct infringers and indirect infringers of its combination drug products that incorporate TAF. TAF generates billions of dollars of revenue for Gilead. Gilead's commitment to enforcing its patents is a matter of public record. And, Gilead has not granted AIDS Healthcare a license or covenant not to sue. These and other undisputed jurisdictional facts firmly establish that AIDS Healthcare's actions make it vulnerable to an infringement challenge, which is all that is necessary for jurisdiction under *MedImmune*.

Gilead claims that its NCE exclusivity prevents this Court from exercising its jurisdiction as there is not a current controversy between Gilead and AIDS Healthcare and AIDS Healthcare would not be subject to suit until the first Abbreviated New Drug Application ("ANDA") is filed. However, it is the NCE exclusivity that makes this dispute ripe for resolution now. Pursuant to TAF's NCE exclusivity, no ANDA can be filed until November 2019. The determination of invalidity AIDS Healthcare currently seeks is likely to take until at least November 2019 to be

confirmed by the Federal Circuit. Given that, on average, patent cases in the Northern District of California take 2.7 years from the filing of a complaint to adjudication at trial (FAC ¶ 24 n.27), it is imperative that AIDS Healthcare act now to ensure prompt approval of the forthcoming ANDAs rather than the FDA delaying ANDA approval pending the outcome of litigation that is not filed until the first ANDA is filed, as Gilead would have it.

Gilead refuses to take the step of disclaiming any right or intention to assert the relevant patents against AIDS Healthcare. That is not surprising. Combination drugs incorporating TAF are expected to generate well over a billion dollars in United States sales for Gilead in fiscal year 2016 alone. (FAC ¶¶ 110-14.) Accordingly, every day that Gilead maintains its patent rights is a day it can protect its enormously lucrative TAF monopoly and "put[] [AIDS Healthcare] in the position of either pursuing arguably illegal behavior or abandoning that which [AIDS Healthcare] claims a right to do"—namely, bring a competing product to market. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007). That is all AIDS Healthcare need show for subject matter jurisdiction.

The Court should not allow Gilead to pretend it has no intention to sue now, only to bring its suit against AIDS Healthcare when generic entry is anticipated. The very purpose of the Declaratory Judgment Act is to provide patent certainty in this type of situation. Gilead's arguments for dismissal of AIDS Healthcare's declaratory judgment claims of patent invalidity disregard controlling law and undisputed jurisdictional facts. They also disregard the established federal "patent-related policy of eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'" *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2233 (2013). Accordingly, the Court should deny Gilead's requests for dismissal pursuant to Rules 12(b)(1) and 12(b)(6).

II. BACKGROUND

The first TAF-containing product, Genvoya, was released by Gilead in November 2015 (FAC ¶ 14); however, TAF is not a new compound. TAF is a prodrug of the compound Tenofovir, which was synthesized over thirty years ago in the Czech Republic. (*Id.* ¶ 98.) Nor was TAF the first prodrug of Tenofovir. Several years before Gilead obtained a patent on TAF, Gilead had

patented a similar prodrug called Tenofovir Disoproxil ("TDF"). Despite similarities between TAF and TDF, TAF is a far superior prodrug formulation of Tenofovir because a smaller dose can be utilized for the same effect, thus reducing bone and kidney toxicity issues. (*Id.* ¶ 8 n.4.) Despite this clinical superiority of TAF, Gilead's patents covering TAF are weak in light of the minor and obvious change in the Tenofovir prodrug. (*Id.* ¶¶ 99-103.) Despite the minor product variation from TDF to TAF and the weakness of its patents covering TAF, Gilead sought to extend the period of patent exclusivity for drugs incorporating Tenofovir by decades. (*Id.* at ¶¶ 8-9.) To achieve prolonged monopoly profits in the markets for TDF, and now TAF, Gilead manipulated patent and FDA law and entered into licensing agreements with Japan Tobacco and Johnson & Johnson subsidiary Janssen Sciences to block entry by potential competitors and prevent competition. (*Id.* ¶¶ 2, 22.)

A. Tenofovir Was First Discovered Over Thirty Years Ago

Tenofovir was discovered in 1984 by scientists in the Czech Republic. (*Id.* ¶ 98.) Gilead bought the rights to sell Tenofovir in 1997. (*Id.* ¶ 99.) The original formulation of Tenofovir held little sales potential, however, because it had to be given intravenously. Gilead scientists modified the chemical composition to create a drug that could be taken orally. The modified chemical composition is Tenofovir Disoproxil ("TDF"). (*Id.* ¶¶ 99, 100.) The Food and Drug Administration approved TDF under the brand name Viread in October 2001. (*Id.* ¶ 101.)

TDF became the backbone of many HIV treatment regimes. The use of multiple drugs to treat HIV is known as Highly Active Antiretroviral Therapy ("HAART"). (*Id.* ¶¶ 4, 46, 142.) HAART is aimed at reducing a patient's viral load and thus maintaining a patient's immune system. HAART regimens generally consist of three drugs: two drugs from the class of drugs known as Nucleoside Reverse Transcriptase Inhibitors ("NRTIs") and one drug from classes of drugs known as Non-Nucleoside Reverse Transcriptase Inhibitors ("NNRTI"), Protease Inhibitors ("PI"), or Integrase Nuclear Strand Transfer Inhibitors ("INSTI"). Tenofovir is an NRTI and is frequently used in HAART therapies. In addition to making TDF available as a standalone drug product under the brand name Viread, Gilead incorporated TDF in fixed dose combination pills including Atripla, Truvada, Stribild, and Complera.

From its introduction, studies of TDF showed that TDF could cause significant kidney damage and bone toxicity. (*Id.* ¶¶ 8, 16.) The toxicity of TDF was particularly alarming as HIV-infected patients were likely to receive treatment for decades, allowing the toxicity to build overtime. When TDF was approved in 2001, the FDA required Gilead to study whether TDF would harm humans.[3] The FDA twice issued warning letters to Gilead, stating that Gilead sales representatives had violated the law by giving doctors and patients false and misleading information regarding TDF's side effects. According to a 2002 FDA Warning Letter, Gilead salespeople had falsely stated that TDF had "no toxicities" was "benign" and was "extremely safe."[4] A 2003 FDA Warning Letter took the unusual step of requiring Gilead to retrain its sales representatives to provide accurate information regarding the significant side effects associated with TDF and comply with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 352.[5]

B. Despite the Toxicity Associated With TDF, Gilead Shelves Research Studies Showing TAF's Superior Safety Profile

In April 2001, working to reduce the side effects of TDF, Gilead scientists published research on a different chemical version of Tenofovir, called Tenofovir Alafenamide ("TAF"). In addition to test tube and animal research studies on TAF, Gilead paid doctors in April 2002 to conduct studies of TAF in HIV patients around the country.[6] However, Gilead did not publish the results of the 2002 studies until 2014. TAF had much higher absorption rates than TDF and avoided the bone and kidney toxicity associated with TDF. (FAC ¶¶ 8, 11.) Gilead pursued patents on TAF

[3] *Food and Drug Administration,* CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW App. No. 21-356 pp. 1-7 (May 1, 2001) (Berger Decl. Ex. B). AIDS Healthcare requests the Court take judicial notice, pursuant to Fed. R. Evid. 201(b)(2) and (c)(2), of FDA filings which are matters of public records and appear on the FDA's website. Gilead requested the Court take judicial notice of "materials that are matters of public record and appear on the FDA's website." (Gilead Br. 4 n.1.)

[4] Laura Pincock, *Warning Letter Regarding Viread Tablets NDA 21-356,* FOOD AND DRUG ADMINISTRATION DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS (March 14, 2002) (Berger Decl. Ex. C).

[5] Thomas W. Abrams, *Warning Letter Regarding Viread Tablets NDA 21-356,* FOOD AND DRUG ADMINISTRATION DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS (July 29, 2003) (Berger Decl. Ex. D).

[6] Martin Markowitz et al., *Phase I/II study of the pharmacokinetics, safety and antiretroviral activity of tenofovir alafenamide, a new prodrug of the HIV reverse transcriptase inhibitor tenofovir, in HIV-infected adults,* J. OF ANTIMICROBIAL CHEMOTHERAPY 69:1362-1369 (2014) (Berger Decl. Ex. E) (Note, the FAC states that human trials using TAF were not conducted until 2011 (FAC ¶ 8); however, subsequent factual investigation uncovered this article showing that human trials were in fact conducted as early as 2002.).

at the same time it publicly claimed that it was discontinuing its development program for TAF. (*Id*. ¶¶ 57-59.) In October 2004, Gilead's CEO John C. Martin announced, "the company is discontinuing its development programs for GS 9005 and GS 7340 [TAF], two investigational products for the treatment of HIV." (*Id*. ¶ 57.) Despite its public statements that it was abandoning TAF, from October 22, 2004 to May 20, 2005, Gilead filed seven patent applications relating to the use of TAF to treat HIV. (*Id*. ¶ 58.)

While Gilead sat on its research regarding the safety of TAF for over a decade, HIV patients were given TDF and exposed to potentially life threatening kidney damage and bone toxicity. (*Id*. ¶ 8.) Not until generic entry into the TDF market was set to commence in 2017 did Gilead decide to pursue TAF, seeking approval for combination drug products containing TAF. (*Id*. ¶¶ 8, 140-142.) HIV patients suffered from 10 years of additional accumulated kidney and bone toxicity using TDF while TAF studies remained unpublished and TAF products remained undeveloped. Gilead's delay in making TAF available was directly related to gaming the patent system and Hatch-Waxman regulatory regime so Gilead could profit while HIV patients were deprived a drug known by Gilead to be a safer alternative to TDF.

When Gilead finally made TAF available, it refused to release TAF as a standalone product. Instead, Gilead entered into licensing agreements with Japan Tobacco and Janssen to sell fixed-dose combination therapies that enjoy the patent protections of not only the weak TAF patents, but also the patents that cover the other pharmaceutical compounds in these combination drugs. (*Id.* ¶ 105.) Gilead made TAF available only as a part of three combination drugs. ***Genvoya,*** a fixed-dose combination tablet containing elvitegravir, cobicistat, emtricitabine, and TAF. Gilead entered into an agreement with Japan Tobacco to license elvitegravir and tie it to the sale of TAF. (*Id*. ¶ 14.) ***Odefsey***, a fixed-dose combination tablet containing emtricitabine, rilpivirine, and TAF. Gilead entered into an agreement with Janssen to license rilpivirine and tie it to the sale of TAF. (*Id*. ¶ 73.) ***Descovy***, a fixed-dose combination tablet containing emtricitabine and TAF. (*Id*. ¶¶ 15-16.)

Gilead's refusal to release a standalone version of TAF deprives AIDS Healthcare physicians of the ability to tailor HAART therapies (including TAF) for patients. Gilead's business practices also

force AIDS Healthcare, as a requirement of obtaining TAF, to purchase quantities of elvitegravir, cobicistat, emtricitabine, and rilpivirine far greater than AIDS Healthcare desires or needs. (*Id*. ¶¶ 17-19.)

C. Gilead's Scheme To Block Competition And Monopolize The Market For TAF

TAF, despite its superior safety profile over TDF, was not a technological breakthrough and is not patentable. (*Id*. ¶¶ 9-10, 84.) At the time TAF was developed, it was well known that formulating antiviral compounds as prodrugs allowed intracellular absorption. The purported inventive step in TAF appears to be the simple process of combing well-known techniques in prodrug formulation with the tenofovir compound that had been known for over a decade as having anti-HIV effects. (*Id*. ¶¶ 103-104, 106, 149-152.).

The weakness of Gilead's patents on TAF led Gilead to adopt anticompetitive business practices aimed at keeping competing TAF drugs off the market for years. (*Id.* ¶¶ 11-15.) Gilead's multipronged scheme to block competition in the TAF market includes: delaying the release of compound therapies containing TAF to coincide with the expiration of Gilead's patents on TDF (*id*. ¶¶ 8, 118); entering into agreements with Japan Tobacco and Janssen that tie any purchase of TAF to the purchase of other drug products (*id*. ¶¶ 5, 12-15, 65, 73); and refusing to release TAF as a standalone drug so that any generic maker will have to challenge not only the patents on TAF, but also the patents relating to the tied drugs (*id*. ¶¶ 102-109).

1. TAF Is Identified And Patented, But Gilead Delays TAF Release In An Anticompetitive Scheme To Maximize NCE Exclusivity To The Detriment Of HIV/AIDS Patients

Gilead timed its application for FDA approval of TAF containing drug therapies to maximize New Chemical Entity Exclusivity ("NCE exclusivity"). Specifically, Gilead waited until TDF was about to go off patent to seek FDA approval and NCE exclusivity for TAF. (*Id*. ¶¶ 8, 118.) NCE exclusivity prevents anyone from filing for FDA approval of any TAF-containing product until late 2019. (*Id*. ¶ 3.) The NCE exclusivity period would already have expired had Gilead not timed its first application for FDA approval of a TAF-containing therapy to be over a decade after it conducted first human trials of TAF. And because Gilead has not sought FDA approval of a standalone TAF indicated for the treatment of HIV, a potential maker of generic TAF

product would need to conduct its own clinical investigations establishing a standalone TAF product's effectiveness for such treatment. *See* 21 U.S.C. § 355(b)(1)-(2). A potential market entrant would need to invest millions of dollars to conduct additional clinical trials to bring a standalone TAF product to market. However, because of TAF's current NCE exclusivity, a potential manufacturer of generic TAF is prohibited from filing a 505(b)(2) application for a standalone version of TAF until at least November 5, 2019. (Gilead Br. 5 (*citing* 21 C.F.R. § 314.108(b)(2)).) Therefore, even after expending significant resources on new clinical investigations, a maker of generic TAF would face an additional three years of delay as Gilead can (and likely will) conduct its own studies of standalone TAF, submit an application for standalone TAF before November 2019, and seek three years of additional exclusivity for the standalone TAF product. *See* 21 U.S.C. § 355(c)(3)(E)(iii). Gilead's actions undermine the Hatch-Waxman Act's regulatory scheme designed to incentivize consumer access to affordable drugs.

2. Gilead, Japan Tobacco, and Janssen Agree To Tie Any Purchase Of TAF To Other Drugs Used In HAART Therapy

Gilead entered into agreements with Japan Tobacco and Janssen to utilize its monopoly power in TAF to force the purchase of complementary drugs used in the treatment of HIV and to block generic TAF entry. Japan Tobacco entered into a series of exclusive licensing agreements with Gilead relating to elvitegravir. (FAC ¶ 65.) The agreements granted Gilead the "exclusive rights to develop and commercialize elvitegravir." (*Id.*) Gilead and Janssen entered into an agreement that tied the availability of TAF to Janssen's rilpivirine in Gilead's fixed-dose combination tablet Odefsey. (*Id.* ¶ 73.) Under the terms of Gilead's agreement with Janssen, the "parties share revenue based on the ratio of set selling prices of the party's component(s)" with Gilead retaining "a specified percentage of Janssen's share of revenues, up to 30% in major markets." (*Id.*)

3. Gilead's Refusal To Make TAF Available As A Standalone Drug Allows Gilead To Shield Weak TAF Patents From Challenge

Defendants' tying scheme allows Gilead to enjoy the patent protection of not just the weak patents covering TAF, but also the patents that cover the other pharmaceutical compounds tied to the sale of TAF. (*Id.* ¶ 12.) Under the Hatch-Waxman regulatory regime, a generic manufacturer entering

the market would have to invalidate the TAF patents as well as the patents that cover the other drug products in the fixed-dose combination therapies. (*Id.* ¶ 105.) Gilead has tactically chosen to not offer a standalone TAF drug so that any generic maker entering the market would be forced to either challenge several patents covering two or more separate pharmaceutical compounds, or go through the years-long and incredibly expensive process of conducting clinical trials. (*Id.* ¶¶ 157-159.)

Gilead's November 2015 release of the brand drug Genvoya (which incorporates TAF) is indicative of the anti-competitive strategy employed by Gilead to protect TAF from a patentability challenge directly. (*Id.*) Genvoya is a fixed-dose combination tablet containing elvitegravir, cobicistat, emtricitabine, and TAF. Because Genvoya contains three drug products in addition to TAF, Gilead is able to list twelve patents as covering Genvoya in the FDA's Orange Book. (*Id.* ¶ 14, 105, 157.) A generic maker looking to enter the TAF market (pursuant to Hatch-Waxman regulations) must prove non-infringement or invalidity of twelve patents versus the three weak patents that are specific to TAF. Gilead's refusal to release a standalone version of TAF is an anticompetitive scheme deliberately designed to block and delay entry of competing versions of TAF. (*Id.* ¶ 160.)

D. AIDS Healthcare's Work Making TAF Available Has Been Disrupted By Gilead's Manipulation Of The Patent System

AIDS Healthcare is the largest non-profit provider of specialized HIV/AIDS medical care in the United States. (*Id.* ¶ 24.) AIDS Healthcare provides large-scale HIV counseling and testing services, early intervention services, HIV medical care, research on HIV care and treatment, medical case management, pharmacy services, referrals, and innovative client retention protocols. (*Id.*) AIDS Healthcare operates 46 Healthcare Centers in the United States spread throughout 14 states and the District of Columbia, including California and Nevada. Worldwide, AIDS Healthcare has 575,000 patients and clients. (*Id.* ¶ 25.)

AIDS Healthcare has taken steps to distribute and purchase generic versions of TAF either as a standalone pill to be used as a part of HAART therapies or as part of a combination drug formulation. The steps taken by AIDS Healthcare include: (1) requesting to place orders with pharmaceutical manufacturers to make a standalone TAF product (*id.* ¶ 31), (2) requesting from Gilead a covenant not to sue AIDS Healthcare relating to its activities directed to bringing generic TAF to market (*id.* ¶¶ 35-36), (3) providing written notice to Teva North America, Autobindo Pharma USA, Lupin

Pharmaceuticals, and Sandoz, that AIDS Healthcare is "ready and able to distribute a generic version of TAF as a standalone compound (that would be used in a combination HIV treatment regime) or a generic tablet containing TAF" (*id*. ¶¶ 33-34), (4) an ongoing study of TAF in treating patients conducted by Otto Yang (Scientific Director for AIDS Healthcare), Michael Wohlfeiler (Chief of Medicine for AIDS Healthcare), and Robert Heglar (Deputy Chief of Medicine for AIDS Healthcare) (*id*. ¶ 47), (5) preparing clinicians and patients for treatments that incorporate generic TAF (*id*. ¶¶ 39, 47), (6) educating the public, government agencies, hospitals, and advocacy organizations about generic TAF (*id*.), (7) preparing for the distribution of HAART therapies incorporating generic TAF (*id*.), (8) notifying Gilead in writing that AIDS Healthcare intends "to manufacture, purchase, import and/or sell tonofovir alafenamide, which Gilead has claimed is subject to patents assigned and/or licensed to Gilead" (*id*. ¶ 36), and (9) conducting analysis of potential combination therapies for HIV that incorporate TAF and drugs that are not part of Gilead's fixed-dose combination tablets (*id*. ¶ 46).

Given these activities, AIDS Healthcare "has a reasonable and real anticipation of legal action should it continue to undertake steps toward securing the manufacture, purchase, and importation" of TAF. (*Id*. ¶ 36.) AIDS Healthcare is in the position of either abandoning its plans and intent to obtain a standalone TAF product or run the risk of being sued for infringement. Faced with this reality and Defendants' continuing anticompetitive actions, AIDS Healthcare brings this suit to stop Defendants from blocking affordable access to a safe version of a lifesaving HIV drug – TAF.

III. LEGAL STANDARD

Despite arguing for dismissal under both Rules 12(b)(1) and 12(b)(6), the same legal standard applies to all arguments raised by Defendants – that is, that all factual allegations contained in AIDS Healthcare's complaint are assumed to be true and all reasonable inferences must be drawn in AIDS Healthcare's favor. First, with respect to Defendants' motion to dismiss Plaintiff's declaratory judgment of patent invalidity claim for lack of subject matter jurisdiction, "[a] Rule 12(b)(1) jurisdictional challenge may be facial or factual." *Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004). Here, Defendants do not argue that the facts AIDS Healthcare alleges are inaccurate; rather, they argue that they are insufficient to confer subject matter

jurisdiction, thus presenting a facial challenge. The Court must "therefore 'assume [plaintiff's] [factual] allegations to be true and draw all reasonable inferences in [its] favor.'" *Doe v. See*, 557 F.3d 1066, 1073 (9th Cir. 2009) (quoting *Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004)). With respect to Defendants' motion to dismiss all claims pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, the allegations of the complaint must be accepted as true and construed in the light most favorable to AIDS Healthcare. *No. 84 Employer-Teamster v. Am. W. Holding Corp.*, 320 F.3d 920, 931 (9th Cir. 2003).

IV. THIS COURT HAS SUBJECT MATTER JURISDICTION OVER THIS ACTION

Gilead challenges subject matter jurisdiction on the grounds that this case does not currently present a justiciable controversy. (Gilead Br. 5.) *MedImmune* dooms Gilead's challenge if "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having:" (1) "adverse legal interests" that (2) are "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127 (citation omitted); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1338 (Fed. Cir. 2007) (explaining that "actual controversy" under the Declaratory Judgment Act has the "same [meaning] as an Article III case or controversy."). The facts existing at the time AIDS Healthcare filed its complaint satisfy this two-part standard. *GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 483 (Fed. Cir. 1996) (citation omitted).

A. This Case Presents A Substantial Controversy Between Parties Having Adverse Legal Interests

The parties have "adverse legal interests." *MedImmune*, 549 U.S. at 127. As long as Gilead's patents remain in force, they can be used to prevent AIDS Healthcare from selling, marketing, and encouraging the development and importation of products that would cut directly into Gilead's multi-billion-dollar monopoly profits on combination drug therapies that incorporate TAF. Gilead does not dispute this. Instead, it argues that this case fails the substantial controversy prong of *MedImmune*'s jurisdictional inquiry because AIDS Healthcare has not shown that "Gilead has threatened or take[n] action adverse to AHF." (Gilead Br. 8.) This argument, which ignores factual allegations in the complaint that meet this standard (*see* FAC ¶¶ 32-45), misstates the law.

MedImmune approved a "more lenient" standard that "facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases." *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008). Accordingly, pleading a "reasonable apprehension" of suit remains "one of many ways" to establish jurisdiction. *Caraco Pharm. Labs, Ltd. v. Forest Labs, Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008). But it is not the only way. As Gilead's own brief concedes, (Gilead Br. 10), AIDS Healthcare can satisfy Article III by pleading that Gilead's conduct "puts [AIDS Healthcare] in the position of either pursuing arguably illegal behavior or abandoning that which [it] claims a right to do." *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007); *see also MedImmune*, 549 U.S. at 129; *Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1357-58 (Fed. Cir. 2013).

1. Jurisdiction Only Requires The Existence Of An "Actual Controversy"

The jurisdictional facts alleged in AIDS Healthcare's FAC, which construed in the light most favorable to AIDS Healthcare, satisfy this test. AIDS Healthcare fears Gilead's patents based on a host of prior lawsuits, Gilead's refusal to license the patents-in-suit, and its public statements about the patent protection of combination drug therapies using TAF. Whether one says this history establishes a reasonable apprehension of an infringement suit or puts AIDS Healthcare "in the position of pursuing arguably illegal behavior," the result is the same. It establishes that this case presents a substantial controversy over matters on which Gilead and AIDS Healthcare are adverse.

2. There Is An Actual Controversy Requiring Judicial Resolution

Gilead also argues there is no "controversy," because it did not make specific threats against AIDS Healthcare. (Gilead Br. 9.) Gilead is wrong. Under the Supreme Court's *MedImmune* decision, specific threats of infringement are not required. Rather, a controversy exists "where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." *SanDisk*, 480 F.3d at 1381 (Fed. Cir. 2007). Here, Gilead has trumpeted its "exclusivity" under its new patents to the entire industry, time and again, and made clear its strategy for TAF depends on excluding all competition. It cannot be heard to threaten the *entirety* of its competitors, and then claim there is no "controversy" when a *particular* competitor seeks adjudication of its rights. (Gilead Br. 2.) The

law does not require AIDS Healthcare to wait for Gilead to sue at its leisure while AIDS Healthcare suffers from the delay.

3. Gilead's Prior Litigious Conduct Concerning The Tenofovir Field

Gilead concedes that "prior litigation is a circumstance to be considered in assessing the totality of circumstances." (Gilead Br. 9 (internal quotations omitted).) Yet, Gilead argues that the Court should ignore its lawsuits because they are not mirror images of this lawsuit. (*Id.*) That argument fails because any litigation that reflects a patentee's "willingness to protect [its] technology" is relevant to the jurisdictional inquiry. *See Vanguard Research, Inc. v. PEAT, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002) (finding Article III controversy based, in part, on related trade secrets misappropriation suit); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987) (same). And, Gilead has engaged in quite a bit of litigation evidencing its "willingness to protect" its monopoly here.[7] The U.S. suits AIDS Healthcare cites in its FAC establish Gilead's commitment to protecting patented technology involving Tenofovir.[8] Gilead tries to dodge this reality by distinguishing these cases as involving claims against different parties, or for different products or patents. (Gilead Br. 6.) But, in the end, these arguments ignore that "[a] specific threat of infringement litigation by the patentee is not required to establish jurisdiction . . . ." *ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011). "Nor is it necessary that a patent holder make specific accusations against either the potential direct infringers or [a manufacturer-seller]." *Arkema*, 706 F.3d at 1357. What matters is whether the suits evidence Gilead's commitment to enforcing its patents, *see Micron Tech., Inc.*, 518 F.3d at 901, which it plainly has.

---

[7] *See Micron*, 518 F.3d at 902 (finding controversy based on "MOSAID's recent public statements and annual reports [which] confirm its intent to continue an aggressive litigation strategy.").

[8] *See e.g.*, FAC ¶¶ 15 n.15 & 16 n.18; *see also Gilead Sciences, Inc., v. Teva Pharms. USA, Inc., et. al.*, Case No. 10-cv-01796, Dkt. No. 1 ¶ 29 (S.D.N.Y.) (infringement action against generic maker seeking to make tenofovir disoproxil fumarate (TDF)); *Gilead Sciences, Inc., v. Lupin Limited*, Case No. 12-cv-06294, Dkt. No. 1 ¶ 13 (S.D.N.Y.) (infringement action against generic maker seeking to make combination drug that incorporated TDF); *Gilead Sciences, Inc., v. CIPLA Ltd.*, Case No. 12-cv-06351, Dkt. No. 45 ¶¶ 19, 44 (S.D.N.Y.) (infringement action against generic maker seeking to make tablets containing TDF).

Gilead further argues that this jurisdiction because Gilead's patents have not yet been directly infringed and that the declaratory judgment AIDS Healthcare seeks is therefore premature. (Gilead Br. 7-8.) However, the Federal Circuit has rejected this argument where, as in this case, the declaratory judgment plaintiff's "potential liability is only for inducing infringement under 35 U.S.C. § 271(b)." *Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1480 (Fed. Cir. 1998). In *Fina Research*, the Federal Circuit rejected the defendant's argument that "direct infringement must have already occurred for there to be an actual controversy predicated only on inducing infringement." *Id.* at 1485-86; *see Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1332 (Fed. Cir. 2003) ("Article III does not preclude an action by a potential defendant for a determination that its conduct does not induce infringement, prior to any acts of infringement having taken place.")

What is necessary for an actual controversy under Article III is that concrete steps have been taken "with the intent to conduct activity" that would induce infringement. *Fina Research*, 141 F.3d at 1485. Resolving the issue of whether a defendant's "ability and definite intention to undertake a potentially infringing activity constitutes sufficient preparation" is a fact intensive, case-by-case, inquiry. *Id.* Here, AIDS Healthcare's current activities of soliciting the manufacture and importation of generic TAF, conducting research relating to generic TAF, investigating HAART regimes incorporating generic TAF, etc., are exposing AIDS Healthcare to liability for inducing infringement of Gilead's patents. AIDS Healthcare is faced with the choice of either abandoning this course of conduct or facing potentially significant liability from Gilead's enforcement of its patent rights.

4. Gilead's Refusal To Grant AIDS Healthcare A Covenant Not To Sue

To date, Gilead "has not granted AHFs request for a covenant not to sue for a claim that AHF's activities give rise to induced and/or direct infringement of patents relating to TAF." (FAC ¶ 35.) These facts are undisputed evidence of a substantial patent controversy. *See, e.g.*, *Arkema*, 706 F.3d at 1358 (finding jurisdiction where patentee declined to issue covenant not to sue); *Arris Group, Inc. v. British Telecommc'ns PLC*, 639 F.3d 1368, 1378 (Fed. Cir. 2011) (explaining that "the nature and extent of any communications between the declaratory plaintiff and the patentee are certainly relevant factors to consider" in determining jurisdiction); *BP Chems. Ltd. v. Union*

Carbide Corp., 4 F.3d 975, 980 (Fed. Cir. 1993) (holding that "a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination" of whether controversy exists), *abrogated on other grounds by MedImmune*, 549 U.S. 118. Gilead neither addresses these authorities nor moots this controversy by representing that it would *not* sue AIDS Healthcare. This fact alone should be enough to demonstrate that Gilead prefers the status quo—to hold its patent monopoly over AIDS Healthcare's head for as long as possible. Gilead itself has asserted that the failure of a patentee to provide a covenant not to sue is strong indicia for a court asserting subject matter jurisdiction.[9]

5. Gilead's Public Statements Regarding Its Patents

Gilead has been far from silent about how it intends to use its patents against those whose competitive products would cut into TAF's market share. "It is the policy of Gilead to enforce its intellectual property rights *to the fullest extent permitted under law*." (FAC ¶ 44 (emphasis added).) Under any objective standard, and particularly when viewed in light of Gilead's litigation history and licensing refusals, AIDS Healthcare would understand these statements to mean that continued pursuit of product approval and marketing would "put[] [AIDS Healthcare] in the position of either pursuing arguably illegal behavior or abandoning that which [AIDS Healthcare] claims a right to do." *SanDisk*, 480 F.3d at 1381. That is all *MedImmune* requires to establish the first (substantial controversy) prong of the jurisdictional inquiry. *See id.*; *Micron Tech., Inc.*, 518 F.3d at 901 (crediting patentee's "recent public statements and annual reports" as evidence of an "aggressive litigation strategy" relevant to jurisdiction). Gilead's reliance on *Impax Labs., Inc. v. Medicis Pharm. Corp.*, No. C-08-0253, 2008 WL 1767044 (N.D. Cal. Apr. 16, 2008), for the proposition that "Defendant's public statements that it would vigorously enforce its patents did not create an actual controversy—*even when the plaintiff had filed an ANDA*" is misplaced. (Gilead Br. 9.) *Impax* is an unpublished opinion with subsequent litigation history (ignored by Gilead) undercutting the proposition advanced by Gilead. Although the *Impax* Court found no subject matter jurisdiction, the parties reached a settlement while the case was on appeal. Subsequently, a

[9] *See Idenix Pharms., Inc. et al v. Gilead Sciences, Inc. et al.,* Case No. 13-cv-01987, Dkt. No. 17 at 16. (D. Del.) ("Moreover, a patentee's failure to provide assurances that it will not enforce its patents is relevant to the determination of an actual case or controversy.").

Federal Court found that allegations that the settlement in which Impax received a payment in exchange for not pursuing its appeal plausibly "served no purpose other than to delay generic competition." *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, Case No. 14-cv-02503-DJC, 2015 U.S. Dist. LEXIS 125999, at *33 (D. Mass. Aug. 14, 2015).

B. The Parties' Controversy Is Real And Immediate

To satisfy the second prong of *MedImmune*—that the controversy be real and immediate—AIDS Healthcare must show only that it has "meaningful[ly] prepar[ed] for making or using" a "substantially fixed" product in the U.S. *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 881-82 (Fed. Cir. 2008). AIDS Healthcare satisfies this burden based on undisputed facts.

In the U.S., the "fixed product" is the one described in AIDS Healthcare complaint, (*see* FAC ¶ 38), which defines precisely what product AIDS Healthcare seeks to market – TAF. Gilead's response would have this Court demand clairvoyance to satisfy the Declaratory Judgment Act. Even though every introduction of an HIV Drug by Gilead has led to the submission of ANDA applications from generic makers following the expiuration of NCE Exclusivity (Berger Decl. Ex. H) – and TAF's predecessor TDF was subject to multiple ANDA filings (FAC ¶ 45), – Gilead pretends that the path forward is entirely uncertain. It says "'some day' intentions fail the requirements of immediacy and reality" (Gilead Br. 2), even though Gilead has actively litigated multiple patent suits related to TDF.[10] Gilead has entered into agreements with its licensee partners such as Japan Tobacco stating that it will "investigate any alleged or *threatened infringement* and assist in the investigation and enforcement," and stated that Gilead's policy is to enforce its "intellectual property rights to the *fullest extent permitted* under law." (FAC ¶¶ 44 (emphasis added).) Gilead argues there is little certainty with respect to whether and when a generic will file an ANDA application on TAF compounds. This argument fails for several reasons.

[10] *Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 276-78 (D. Mass. 2006) (finding the presence of a controversy when expected approval date was 20 to 24 months away); *Boston Scientific Corp. v. Johnson & Johnson Inc.*, 532 F. Supp. 2d 648, 653 (D. Del. 2008) (finding jurisdiction in 2007 action when product expected to be launched in 2008); *Glaxo Grp. Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1007 (N.D. Ill. 2001) (finding actual controversy despite FDA approval period of up to two years).

First, all of Gilead's arguments confuse the existence of a live controversy now (which is what matters for jurisdiction over the complaint) with whether future events could moot that controversy later. *See Dey Pharma, LP v. Sunovion Pharm. Inc.*, 677 F.3d 1158, 1165 (Fed. Cir. 2012) ("there is a difference between finding that a controversy exists to initiate a suit and determining that the controversy has become moot"). Right now, Gilead's enforcement posture "puts [AIDS Healthcare] in the position of either pursuing arguably illegal behavior or abandoning that which [it] claims a right to do," namely, proceed with preparing and marketing generic TAF drugs. *MedImmune*, 549 U.S. at 129; *SanDisk*, 480 F.3d at 1381. Subjective speculation about the timing of an ANDA filing (Gilead Br. 2) cannot overcome the well-pled factual allegations in the complaint that such filings are likely in 2019, (*see, e.g.*, FAC ¶ 118).

Second, Gilead's actions today have real and immediate impact on AIDS Healthcare. As the complaint makes clear: (1) AIDS Healthcare researchers Otto Yang, Michael Wohlfeiler, and Robert Heglar are "conducting an ongoing study of TAF in treating patients;" however, "the litigation threat by Gilead has had a chilling effect on chilling effect on AHF being able to continue its investigation and preparation for distributing generic TAF" (FAC ¶¶ 46, 47); (2) AIDS Healthcare has conducted analysis of "potential combination therapies for HIV that incorporate TAF" as a standalone product with untied drug compounds (*id.* ¶ 46); (3) Gilead's history of entering into "pay-for-delay" settlements with generic makers require AIDS Healthcare to clear the "invalid patents that Gilead has obtained . . . to ensure generic entry" (*id.* ¶¶ 42-43); (4) Gilead's activities and the threat of litigation are presently causing AIDS Healthcare to forgo "preparing clinicians and patients for treatments," "educating the public, government agencies, hospitals, and advocacy organizations," "working with suppliers to manufacture TAF," "research activities," "preparing for the distribution of HAART therapies incorporating generic TAF," and "conducting investigations regarding the use of generic TAF" (*id.* ¶ 39); (5) Gilead's "patent scheme[]" harms AIDS Healthcare by "artificially propp[ing] up pricing for branded drugs such as Genvoya, Odefsey and Descovy" (*id.* ¶ 79, 114); and (6) Gilead's maintenance of patents "prevents AHF from providing efficient treatment options that are tailored to its patients" (*id.* ¶ 115).

Third, although the first direct infringement of the Gilead patents is likely to occur in three years, that is in keeping with the time horizons found to create a sufficiently immediate case or controversy. *See e.g.*, *Amgen, Inc. v. F. Hoffman-LaRoche Ltd*., 456 F. Supp. 2d 267, 276-78 (D. Mass. 2006) (finding the presence of a controversy when expected approval date was 20 to 24 months away); *see Boston Scientific Corp. v. Johnson & Johnson Inc.*, 532 F. Supp. 2d 648, 653 (D. Del. 2008) (finding jurisdiction in 2007 action when product expected to be launched in 2008); *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1007 (N.D. Ill. 2001) (finding actual controversy despite FDA approval period of up to two years).

Fourth, that a declaratory judgment claim is dependent on future contingencies does not automatically deprive the Court of the power to adjudicate an existing case or controversy. As the Tenth Circuit stated in explaining the Supreme Court's decision in *Maryland Cas. Co.* v. *Pacific Coal & Oil Co.,* 312 U.S. 270 (1941), "Even the existence of contingencies did not prohibit the Court from issuing a declaratory judgment in that case." *Kunkel v. Continental Cas. Co.,* 866 F.2d 1269, 1274 (10th Cir. 1989). "A plaintiff need not suffer a completed harm to establish adversity of interest. . . . In some situations, present harms will flow from the threat of future actions.'" *Peco Energy Co. v. Twp. of Haverford,* Case No. 99-4766, 1999 U.S. Dist. LEXIS 19409, *11 (E.D. Pa. Dec. 20, 1999) (quoting *Armstrong World Indus. v. Adams,* 961 F.2d 405, 412 (3d Cir. 1992)).

Fifth, AIDS Healthcare, as the largest non-profit provider of specialized HIV/AIDS medical care in the United States, is harmed in ways that are uncontemplated in the cases relied on by the Defendants. AIDS Healthcare operates pharmacies, conducts HIV research, educates the public, and lobbies public organizations, among other activities. AIDS Healthcare purchases hundreds of millions of dollars of HIV medication on behalf of its patients, employs over 3,350 people dedicated to preventing and treating HIV/AIDS, operates 46 healthcare centers, and is responsible for providing services to 575,000 patients and clients. AIDS Healthcare's interests are a stark and material distinguishing factor to those of the parties referenced in Defendants' recitation of case law. (FAC ¶¶ 24-29.) For example, Gilead's reliance on the following cases are easily distinguishable from the facts pled in AIDS Healthcare's complaint.

- *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274 (Fed. Cir. 2014), is cited repeatedly by Gilead for the alleged proposition that absent a concrete act of infringement, dismissal is required. However, the Court's holding was based on Sandoz's failure to show that it would "suffer an immediate and substantial adverse impact from not being able to seek or secure a patent adjudication before filing an application for FDA approval." *Id*. at 1281-82. Further, Sandoz failed to "argue[] to us that it is suspending or even delaying this investment until a patent adjudication occurs or that it would do so upon receiving an adverse patent judgment." *Id*. at 1282. In contrast, AIDS Healthcare has pled that it will "delay[] or forestall[] AHF's plans" in six areas of investment (FAC ¶ 39) and "suspend plans to distribute generic TAF" (*Id*. ¶ 40).
- *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329 (Fed. Cir. 2008), is cited by Gilead for the proposition that "affirming dismissal where defendants have not accused Prasco of infringement or asserted any rights to [Prasco's product], nor have they taken any actions which imply such claims." (Gilead Br. 8.) However, Gilead neglects to include the subsequent sentence from the Prasco decision, which provides a complete view of the Court's holding. The Court continued, "all we have before us is Prasco's allegation that its product does not infringe the defendants' patents." *Id*. 1340. Further, multiple Courts have limited the holding in *Prasco* to situations where a declaratory judgment plaintiff sought relief based on only a plaintiffs' allegation that it does not infringe the challenged patents. See *IPS Corp. v. WCM Indus.*, 2013 U.S. Dist. LEXIS 45464, at *23 (W.D. Tenn. Mar. 29, 2013) ("*Prasco, LLC*, however, addressed circumstances that are materially different from the case presently before this Court. In *Prasco, LLC*, the Federal Circuit did not find jurisdiction because 'all we have before us is Prasco's allegation that its product does not infringe the defendants' patents.'").[11]

[11] *See also Panda Apparel, LLC v. Spirit Clothing Co.*, 2015 U.S. Dist. LEXIS 119536, at *12 (D.N.J. Sep. 8, 2015) ("[T]he sole case relied on in the Dismissal Order is distinguishable. As Panda correctly points out, in *Prasco* the court held that 'one prior suit concerning different products covered by unrelated patents is not the type of pattern of prior conduct that makes reasonable an assumption that [the patent holder] will also take action against [the plaintiff] regarding its new product.'"); *Activevideo Networks, Inc. v. Trans Video Elecs. Ltd.*, 975 F. Supp. 2d 1083, 1093 (N.D. Cal. 2013) (The Federal Circuit "did not hold that there must be such

- *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1349 (Fed. Cir. 2007), Gilead mischaracterizes as holding that where a party "'merely' had plans to shortly begin potentially infringing actions" dismissal was warranted. (Gilead Br. 7). Gilead again fails to inform the Court of the true basis for the dismissal in *Benitec*. In *Benetic*, the basis for the dismissal was Nucleonics's admission that it might not ever enter the market. *See e.g., Epos Tech. LTD. v. Pegasus Techs. LTD.*, 636 F. Supp. 2d 57, 61-62 (D. D.C. 2009) ("Nucleonic did not anticipate filing an NDA, however until 'at least 2010-12, if ever,' and its current activities consisted entirely of developing and submitting (unidentified) preliminary information to the FDA [activities exempt from infringement under 271(e)]").

1. The Hatch-Waxman Act Does Not Preclude Subject Matter Jurisdiction

It is well settled that "[w]hen there is an actual controversy," "in the usual circumstance" the Court should hear the case. *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993), *abrogated on other grounds*, *Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995). Faced with a justiciable controversy, Gilead asks the Court to deny subject matter jurisdiction because no direct infringement of the patents-in-suit will occur until an ANDA filing in 2019 following the expiration of TAF's NCE exclusivity. But Gilead ignores the repeated cadence of controlling precedent that requires courts to facilitate the fastest route to resolve patent validity, including through exercise of the declaratory judgment remedy. That precedent is particularly controlling here because "[t]here is a *stronger* public interest in the elimination of invalid patents than in the affirmation of a patent as valid"—especially for a drug that generates billions of dollars of revenue. *Nestier Corp. v. Menasha Corp-Lewisystems Div.*, 739 F.2d 1576, 1581 (Fed. Cir. 1984) (emphasis added).

Thus, "[t]here must be well-founded reasons for declining to entertain a declaratory judgment action," especially in "[t]he field of patent litigation," which "is particularly adapted to declaratory resolution." *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355, 1357 (Fed. Cir. 2004). Gilead attempts to manufacture such reasons here by arguing that the Hatch-Waxman Act controls the procedure for resolving any patent disputes and any judicial finding contrary to Hatch-

---

apprehension before there can be a case or controversy. Indeed, such a holding would be contrary to *MedImmune*, the Supreme Court case that preceded *Prasco*.").

Waxman must "be rejected as a matter of law because they are inconsistent with the governing Hatch-Waxman statute." (Gilead Br. 18.) These arguments fail because the Hatch Waxman Act does not govern AIDS Healthcare's conduct. *See* Part IV.B.3, *infra*. It does not prevent Gilead from suing AIDS Healthcare anymore than it prevents AIDS Healthcare from suing Gilead. Nor, even if the Hatch-Waxman Act did apply, would it prevent this suit from continuing. *See* Part IV.B.3, *infra*.

Gilead's Hatch-Waxman Act argument is merely an attempt to convince the Court to leave AIDS Healthcare, a putative indirect infringer, "helpless and immobile so long as [Gilead] refuse[s] to grasp the nettle and sue." *Capo*, 387 F.3d at 1357-58. As Federal Circuit precedent has long recognized, district courts abuse their discretion by putting a putative infringer in such an untenable position. *See, e.g.*, *id.*; *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1347 (Fed. Cir. 2005) (reversing where district court, in dismissing suit, focused too much on the anticipatory nature of the controversy); *Minnesota Min. & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 676 (Fed. Cir. 1991) (same where declination of jurisdiction gave too much weight to pending interference proceeding and too little weight to harm of delay).

2. This Case Serves The Purposes Of The Declaratory Judgment Act.

Dismissing this case would frustrate the purpose of the Declaratory Judgment Act by allowing Gilead to disrupt AIDS Healthcare's ability to determine its rights. If AIDS Healthcare were forced to wait until after the filing of an ANDA to file suit, the lawsuit could not determine AIDS Healthcare's right to a declaratory judgment before product launch. By filing now, AIDS Healthcare gives the Court adequate time to hold trial and issue judgment before generic launch rather than either prolonging an unwarranted monopoly over a lifesaving drug or resolving the dispute in an emergency hearing. Maintaining this action thus advances sound judicial administration. Gilead is thus left to argue for dismissal under the Hatch-Waxman Act.

3. The Hatch-Waxman Act Presents No Jurisdictional Bar To This Suit

For all of the foregoing reasons, this Court has jurisdiction under controlling law. And because the core facts that AIDS Healthcare relies upon for jurisdiction are undisputed, there is no need for jurisdictional discovery. *See Sanderson v. Horse Cave Theatre 76*, 881 F. Supp. 2d 493,

502 (S.D.N.Y. 2012) ("On a motion to dismiss pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, the non-conclusory factual allegations in the complaint, unless contradicted by evidence, are taken as true and all reasonable inferences drawn from those factual allegations are construed in favor of the plaintiff.").

Forcing AIDS Healthcare to wait until the lapse of the NCE exclusivity term to proceed on its invalidity claims would grant Gilead an additional exclusivity the Hatch-Waxman Act does not afford. In the ordinary operation of the Act, a product under NCE exclusivity receives 5 years of exclusivity. After the first four years, a generic applicant can file its own ANDA application, leaving a four year period for patent resolution under the Hatch-Waxman Act. Requiring the filing of an ANDA before the roughly three year litigation process would give the NCE drug owner a new and unwarranted three year exclusivity extension. That extra delay cannot be what Congress intended, especially where the exclusivity pertains to patents alleged to be invalid. *See, e.g.*, *Nestier Corp.*, 739 F.2d at 1581 ("[t]here is a *stronger* public interest in the elimination of invalid patents than in the affirmation of a patent as valid") (emphasis added).

Gilead argues this case should await an ANDA filing because the Hatch-Waxman Act supposedly reflects a Congressional intention to delay patent litigation until after FDA filings are made. If this statement were true, however, there would be statutory provisions confirming it. Tellingly, Gilead cites no provision in the statute purporting to deprive the federal courts of subject matter jurisdiction where a case or controversy is already established prior to the time of an FDA filing. There is none.

Here, the FDA can accept and review ANDA applications on TAF-containing products beginning in 2019. Thus, AIDS Healthcare can market TAF combination therapies immediately upon FDA approval, which could occur in as little as 12 months after filing. Because a complex pharmaceutical patent case cannot be resolved in 36 months, the *only way* for the parties to achieve patent certainty prior to commercial marketing in this case is through a declaratory judgment action brought prior to the ANDA filing.

It makes no sense to delay the start of a declaratory judgment action to a time that undermines the legislative purpose of the rights being adjudicated. Yet that is precisely the result

Gilead seeks here. Perhaps Gilead hopes, given its patent threat, AIDS Healthcare will not make the substantial investments needed to effectively distribute and prepare for generic entry of TAF. Perhaps Gilead hopes that AIDS Healthcare will refrain from inducing infringement until the case is resolved, for fear of incurring a potential damages claim. In either situation, Gilead will have extracted an unjustified benefit by holding AIDS Healthcare's rights unresolved. This action is necessary and appropriate to relieve AIDS Healthcare from this potential prejudice.

Finally, maintaining this case is appropriate for practical reasons. If this case were delayed until an FDA filing, the court would have to resolve the parties' rights in a preliminary injunction hearing prior to AIDS Healthcare's intended product launch without the benefit of a full record or completed discovery. Accepting jurisdiction now promotes sound judicial administration. It is also consistent with a wealth of judicial experience under the Hatch-Waxman Act, where courts routinely schedule trials to allow for patent issues to be resolved prior to the conclusion of the regulatory stay and intended product launch. *See e.g., Shire LLC v. Amneal Pharm., LLC*, No. 11-3781, 2013 WL 1932927, *7 (D. N.J. 2013) (striking supplemental expert report where the effect of the report would "disrupt this litigation" by preventing the case from being concluded before 30-month stay of the FDA's ANDA approval expired); *Cephalon, Inc. v. Impax Lab., Inc*., No. 11-1152, 2012 WL 3867568, *2 (D. Del. 2012) (denying stay request because "the court could not resolve the present dispute within thirty months if the remaining claims are stayed").

4. Japan Tobacco's Arguments Regarding AIDS Healthcare's Standing To Challenge The '219 Patent Fail

Japan Tobacco's arguments are largely duplicative of the arguments made by Gilead in requesting this court find AIDS Healthcare lacks standing to challenge the patents-in-suit. AIDS Healthcare incorporates its arguments against Gilead's motion by reference. To the extent that Japan Tobacco presents any new issues, it argues that AIDS Healthcare has not identified any present infringing activity that would fall "within the scope of the '219 patent." However, like Gilead, Japan Tobacco has denied AIDS Healthcare's request for assurances it will not sue AIDS Healthcare for direct or induced infringement of the '219 patent. Japan Tobacco's citation of *Cat Tech,* 528 F.3d at 881, underscores AIDS Healthcare's standing to challenge the '219 patent. (Dkt. No.

80 ("Japan Tobacco Br.") 3.) In *Cat Tech.*, the Federal Circuit found that "meaningful preparations" that confer declaratory judgment jurisdiction include "preparation to conduct potentially infringing activity" and that a plaintiff need not show "[it] has prepared draft sales literature or otherwise disclosed its products to potential customers." *Cat Tech*, 528 F.3d at 883. The complaint establishes multiple bases for finding that AIDS Healthcare has conducted meaningful preparations including: internal studies, lobbying efforts, contacting generic pharmaceutical makers, publically soliciting infringing pharmaceuticals from generic makers, etc. (*See* Part II.D, *supra*.).

V. THE COMPLAINT DOES NOT WARRANT DISMISSAL UNDER RULE 12(B)(6)

Gilead elevates form over substance and practical sense in arguing that AIDS Healthcare's invalidity claims must be dismissed for failure to include details that this Court's local patent rules do not require AIDS Healthcare to provide until later in the litigation. (Gilead Br. 11); *see* N.D. Cal. L. Pat. R. 3-3 (providing a schedule for the disclosure of "Invalidity Contentions."). Emphasizing that pleading requirements should not be used to undermine or supersede such rules, several post-*Iqbal* decisions uphold invalidity claims identical or nearly identical to AIDS Healthcare's, (FAC ¶¶ 10, 23, 146-153), under Rule 8. *See, e.g., Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 937-38 (N.D. Ill. 2010); *Microsoft Corp. v. Phoenix Solutions, Inc.*, 741 F. Supp. 2d 1156, 1159 (C.D. Cal. 2010); *Elan Pharma Int'l Ltd. v. Lupin Ltd.*, No. 09-cv-1008, 2010 WL 1372316, at *4 (D.N.J. Mar. 31, 2010); *Teirstein v. AGA Med. Corp.*, No. 08-cv-0014, 2009 WL 704138, at *4-5 (E.D. Tex. Mar. 16, 2009). In addition, the allegations in the complaint are more than sufficient at the pleadings stage to sustain a claim of invalidity. The complaint identifies relevant prior art and bases for invalidity. (FAC ¶¶ 9, 84-86, 100, 106, 149-153).

That said, even if the Court were to adopt the pleading standard Gilead urges, the alleged deficiencies in Gilead's invalidity claims could easily be cured by amendment or supplement. *See, e.g.*, *Rockwell Automation, Inc. v. Beckhoff Automation, LLC*, 23 F. Supp. 3d 1236, 1248 (D. Nev. 2014) (rejecting motion to dismiss on Rule 8 grounds because plaintiff will receive invalidity contentions). Because AIDS Healthcare is eager to proceed quickly, it is willing to accelerate the schedule for disclosing invalidity contentions. In fact, AIDS Healthcare is so committed to speedy resolution of its claims that it intends to request leave to file an early, pre-discovery motion for

summary judgment on the patents-in-suit. When it does, Gilead will have more than mere contentions—it will have AIDS Healthcare's argument, with more detail than any Rule 8 pleading requirement could possibly be construed to require. AIDS Healthcare could even file that motion *before* Gilead has to answer. Accordingly, the Court should not dismiss this suit for failure to state a claim even if it adopts the pleading standards advocated in Gilead's motion.

VI. AIDS HEALTHCARE HAS STATED A CLAIM FOR TYING UNDER SHERMAN ACT § 1

The complaint alleges that Gilead possesses a monopoly in the foremarket for TAF – it is currently the only manufacturer of TAF. Gilead uses its dominance in TAF to condition the sale of TAF on the purchase of elvitegravir, cobicistat, emtricitabine, and rilpivirine, which are part of the aftermarket for complimentary drugs to antiretroviral medication used in HAART regimens. The complaint specifically alleges Gilead has entered into licensing agreements with Japan Tobacco and Janssen to harm aftermarket competition for drugs used in combination HAART therapies. To prevail on these claims pursuant to Section 1 of the Sherman Act, AIDS Healthcare must show: (1) there was an agreement, conspiracy, or combination between two or more entities; (2) the agreement was an unreasonable restraint of trade under either a *per se* or rule of reason analysis; and (3) the restraint affected interstate commerce." *American Ad Mgmt. v. GTE Corp.*, 92 F.3d 781, 784 (9th Cir. 1996).

Despite all the rhetoric about maintaining "important therapeutic benefits," and "providing an integrated treatment regime for HIV-1 infection" (Gilead Br. 3-4), Gilead does not seek to dismiss AIDS Healthcare's tying claim by defending the reasonableness of its decisions. In fact, Gilead does not challenge AIDS Healthcare's allegation that the agreements lock out competitive alternatives and generic aftermarket combination drug regimes. Nor does Gilead rebut AIDS Healthcare's allegation that limiting clinicians' and patients' ability to design tailored drug therapy regimes harms and limits patients' choice. (FAC ¶ 13.) Finally, Gilead does not deny that this type of predatory arrangement could be an actionable antitrust violation. Instead, Gilead contends that AIDS Healthcare "does not plead any facts supporting a conclusion that TAF is actually a separate product in a different market." (Gilead Br. 25.) In advancing that argument, Gilead concedes that the law recognizes single-branded foremarkets as relevant markets for antitrust claims. Its

objection to AIDS Healthcare's defined foremarket and aftermarket is that it is the FDA's policy to encourage the use of combination therapies for AIDS/HIV treatment. (Gilead Br. 4.) Gilead is wrong. Consumers are harmed by Gilead's attempt to monopolize the aftermarket. Gilead's cherry-picked and out-of-context citations to guidance from the FDA is irrelevant to dismissal of AIDS Healthcare's antitrust claims; the FDA guidance Gilead relies upon as well as other FDA guidance contradict Gilead's argument. The FDA has not sanctioned Defendants' illegal, anticompetitive conduct.

A. AIDS Healthcare Has Pled Two Different Products In Two Distinct Markets

AIDS Healthcare's complaint identifies two separate products in two distinct markets. The first product market is TAF. Gilead enjoys market power in this market by being the only seller of TAF. Gilead's Motion to Dismiss fails because it presents (1) a *factual challenge* to AIDS Healthcare's market definition that, if it has any merit at all, must await determination once a factual record has been established, (2) an inaccurate contention that because TAF is not currently on sale as a standalone product, it cannot be a separate product with a distinct market, and (3) a challenge to AIDS Healthcare's interpretation of separate products that relies on a misinterpretation of Ninth Circuit precedent and an avoidance of contradicting authority. None of these arguments have merit.

The Supreme Court in *Jefferson Parish* held that the question of distinct markets and products "turns not on the functional relation between them, but rather on the character of demand for the two items"—i.e. whether consumers seek the items separately. *Jefferson Parish Hospital District No. 2 v. Hyde*, 466 U.S. 2, 19 (1984). On the basis of this approach, if there exists separate demand for two products, then the products are necessarily separate.[12]

1. The Complaint Alleges Separate Products In Separate Product Markets

The long standing approach to determining whether there are two separate products in two separate product markets is to analyze "the character of the demand for the two items." *Jefferson Parish*, 466 U.S. at 19 (footnote omitted). In *Jefferson Parish*, the Court held that anesthesiological

[12] For instance, applying the *Jefferson Parish* test, the District Court in the *Microsoft* case found that "the commercial reality is that consumers today perceive operating systems and browsers as separate 'products,' for which there is separate demand." *United States v. Microsoft Corp.*, 87 F Supp 2d 30, 49 (D.D.C. 2000).

services were separate from hospital services because there was a "sufficient demand for the purchase of anesthesiological services separate from hospital services to identify a distinct product market in which it is efficient to offer anesthesiological services separately from hospital services." *Id*. at 21-22 (footnote omitted); *see also Drinkwine v. Federated Publ'ns, Inc.*, 780 F.2d 735, 741 (9th Cir. 1986) (separability is "a question of character of demand"); *Digidyne Corp. v. Data Gen. Corp*., 734 F.2d 1336, 1339 (9th Cir. 1984) (separability established by demand for tied product), *cert. denied*, 473 U.S. 908 (1985). The complaint alleges two distinct products in two distinct markets based on multiple allegations that are more than sufficient at the pleading stage. *See In re ATM Fee Antitrust Litig.*, 768 F. Supp. 2d 984, 998 (N.D. Cal. 2009) (Alsup, J.) (denying a motion to dismiss where a deposit account and an ATM card, although issued together and functionally useful in tandem, were alleged to be distinct products). Six independent bases are pled in the complaint supporting the conclusion that TAF is a distinct product in a single-branded market.

First, the complaint pleads that TAF "does not exhibit significant positive cross-elasticity with respect to . . . other products" arising from "TAF's pharmacological profile" which has "lower rates of impaired kidney function" "(FAC ¶¶ 8, 11, 16, 121-125). Even Gilead's own motion describes TAF as a "brand new, superior molecule." (Gilead Br. 4.)

Second, Gilead itself describes TAF as having a distinct consumer demand driven by TAF's superior safety profile. "This is important because most newly diagnosed patients will now be treated for decades." (FAC ¶ 4.) Gilead documents treat TAF as driving demand unto itself "We look forward to introducing this new generation of TAF single tablet regimens that we have created to address the evolving needs of people living with HIV. TAF is a novel targeted prodrug of tenofovir that has demonstrated high antiviral efficacy similar to and at a dose less than one-tenth that of Viread."[13] Further, Gilead presentations identify TAF as driving demand and having its own demand. *See* Gilead Q3 2015 Earnings Results at 8 (October 27, 2015) (Dkt. No. 81-3) (showing TAF driving multiple pipeline milestones for Gilead).

Third, the FDA's 2014 NCE exclusivity interpretation (which are the subject of request for judicial notice proffered by Gilead in its motion to dismiss) and Gilead's own public FDA filings

[13] Gilead 2015 Form 10-K at 7 (Dkt. No. 81-5).

regarding fixed-dose combination tablets support the conclusion that TAF is a distinct product with distinct demand.[14] In 2013, Gilead petitioned the FDA to change the FDA's interpretation on how it awards NCE exclusivity for combination therapies. At the time Gilead filed its petition seeking a change in NCE exclusivity, the FDA's long-standing rule was that combination therapies had to be viewed as a whole drug product (which, for combination products included all constituent drug components) for the purpose of determining where NCE exclusivity was warranted. Gilead, in its citizen petition, stated "the best reading of the statute – and the one that best reflects the agency's rulemaking choices – is that for a 505(b) application that contains a fixed dose combination of drugs, the exclusivity *must be analyzed and granted as to each drug* that is the subject of the application." Berger Decl. Ex. F [Gilead Citizen Petition] at 16 (January 8, 2013).[15] In interpreting the NCE exclusivity provisions (later adopted by the FDA), Gilead argued (and AIDS Healthcare agrees) that the term "new chemical entity" which describes TAF is "a thing with distinct and independent existence:"

> Next, as a matter of plain and common usage, the term "new chemical entity" communicates the idea of a single chemical structure, rather than a combination or grouping of structures. If the agency had intended to include combinations of ingredients, it would not have used a singular term. *The agency chose a term. "entity." that is commonly understood to mean: a thing with distinct and independent existence*. See Dictionary, or something with an independent, separate, or self-contained existence. *See* Merriam- Webster Dictionary. All of these meanings align with the idea of an individual drug substance.

Berger Decl. Ex. F [Gilead Citizen Petition] at 20 (January 8, 2013) (emphasis added).

AIDS Healthcare's identification of TAF as a distinct product within fixed combination formulations comports with Gilead's own interpretation of what defines a drug product. Specifically, Gilead, in its Citizen Petition seeking NCE exclusivity for Stribild, stated:

> Gilead's interpretation is also consistent with how the Patent and Trademark Office analyzes eligibility for patent term extensions on an ingredient-by-ingredient basis

---

[14] *Citizen's Petition submitted by Hogan Lovells, on behalf of Gilead Sciences, Inc.* ("Gilead Citizen's Petition"), requesting 5-year NCE exclusivity for cobicistat and elvitegravir (NDA 203100) (FDA-2013-P-0058) (submitted January 8, 2013) (Berger Decl. Ex. F). AIDS Healthcare requests the Court take judicial notice, pursuant to Fed. R. Evid. 201(b)(2) and (c)(2), of Gilead's FDA filings which are matters of public records and appear on the FDA's website. Gilead requested the Court take judicial notice of "materials that are matters of public record and appear on the FDA's website." (Gilead Br. 4 n.1.)

[15] Gilead's citizen's petition sought NCE exclusivity for two constituent drug products within Stribild (a four drug combination therapy including TDF). *See* Berger Decl. Ex. F.

> for products that contain more than one active ingredient. . . . For patent term restoration, ***Congress achieved that result through a new section in Title 35 that defines "drug product" to mean active ingredient, whether approved "as a single entity or in combination with another active ingredient.***"

Id. at 25 (emphasis added).

The FDA adopted Gilead's interpretation. The TAF-containing fixed dose combination tablets that are at issue here (*e.g.*, Genvoya) were granted NCE exclusivity based on this FDA guidance for which Gilead advocated (looking at each drug in the combination therapy as a "discreet" product). Gilead's contradictory position in the current litigation is a tactical, self-serving position that reflects Gilead's attempt to avoid antitrust liability. As Gilead's petition to the FDA evidences, Gilead wants the FDA to look at drugs in a combination therapy on a drug by drug basis when it will expand Gilead's exclusivity period. Yet, when faced with the same analysis in this Court, Gilead seeks to have the fixed combination tablet evaluated as a whole.

Fourth, Gilead has entered into licenses that provide further evidence that under the consumer demand test, TAF is a distinct product based on demand for TAF. *See* Gilead Q3 2015 Earnings Results at 48 (October 27, 2015) (Dkt. No. 81-3) (announcing new agreement with MPP to expand access to the investigational drug TAF for HIV and HBV, contingent on U.S. regulatory approval); Gilead 2015 Form 10-K at 16 (Dkt. No. 81-5) ("In 2014, we granted certain of our Indian partners direct licenses to produce and distribute generic TAF in the developing world."). In addition, in licensing TAF to Japan Tobacco and Janssen, TAF was treated as a distinct product with distinct consumer demand. *See* Berger Decl. Ex. I [Gilead Japan Tobacco Fourth Amendment to License Agreement] at 1 (July 5, 2011) ("JT and Gilead have previously entered into a license agreement . . . relating to the development and commercialization of FTC, TDF, Truvada and GS-7340 [TAF]."); *See also* Gilead 2014 Form 10-K at 163 (Dkt No. 35-2) (providing a license to Janssen to distribute "the TDF Single Agent Product or the ***TAF Single Agent Product***, but not in combination with other compounds or products.") (emphasis added).

Fifth, products in the same field (although not in the same market as TAF) show that TAF is the "type of product" that has a distinct consumer demand and attendant market. Specifically, the complaint alleges that TAF is in the same field as TDF which is distributed as a "standalone tenofovir TDF product (Viread)." (FAC ¶ 157.) Further, Viread's commercial success as a

standalone tenofovir product is further evidence of consumer demand for TAF as a standalone product. In the first nine months of 2015 alone, Gilead sold $802 million dollars of Viread (Dkt. No. 81-3 at 53), and sold a total of $1.1 billion dollars in all of 2015. (Dkt. No. 81-5.)

Sixth, Gilead's plan to release a standalone version of TAF with a treatment indication for hepatitis B virus infection ("HBV") is further indicia that TAF has a distinct consumer demand. *See* Gilead Form 10-K at 15 (Dkt. No 35-2) (identifying a standalone version of TAF to be released for the treatment of HBV).

The complaint pleads separate and distinct product markets under the purchaser-demand test which requires that there be "a sufficient demand for the purchase of the tied product separate from the tying product to identify a distinct product market." *Nicolosi Distrib., Inc. v. BMW of N. Am.*, No. C 10-03256 SI, 2011 U.S. Dist. LEXIS 44544, at *10 (N.D. Cal. Apr. 19, 2011) (citing *Rick-MikEnters., Inc. v. Equilon Enters. LLC*, 532 F.3d 963, 975 (9th Cir. 2008), and *Corwin v. LA Newspaper Serv. Bureau, Inc.*, 4 Cal. 3d 842, 858-59 (1971)). Under the purchaser demand test, the court looks to "direct and indirect evidence of consumer demand for the tied-product separate from the tying product." *Rick-Mik Enters.*, 532 F.3d at 975 (9th Cir. 2008) (citation omitted). Here, direct evidence shows that "when given a choice, consumers purchase the tied good from the tying good maker, or from other firms." *Id*. For example, here the tied products elvitegravir, cobicistat, emtricitabine, and rilpivirine are each available as standalone products Vitekta, Tybost, Emtriva, and Norvir, respectively. Gilead 2015 Form 10-K at 9-10, 160 (Dkt. No. 81-5) (identifying standalone version of the tied products that are sold by Gilead or other firms). Indirect evidence shows that drugs such as TDF that are in the same field as TAF are sold without being tied to other drug products.

2. Gilead's Failure To Seek FDA Approval For Standalone TAF Does not Preclude Antitrust Liability

Ignoring the applicable case law and the facts properly alleged in the FAC, Gilead argues that AIDS Healthcare cannot allege that TAF is a distinct product for a tying claim as the distribution of TAF is precluded by FDA regulations. (Gilead Br. 26.) But Gilead's argument is erroneously premised on the notion that no antitrust claim could ever be asserted here because no

party has yet pursued FDA approval to market a standalone version of TAF. The law does not support Gilead's wishful conclusion.

First, case law is consistent in holding that FDA approval is not a prerequisite to state an antitrust claim premised on an anticompetitive agreement that ties the distribution of two products. The fact that the tying product currently lacks FDA approval as a standalone product does not mean that the tying product is not a product. Multiple cases hold that the existence of a regulatory regime that does not preclude the tying of two otherwise separate products does not immunize a party from antitrust law. *See MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1103 (7th Cir. 1983) ("The mere pervasiveness of a regulatory scheme does not immunize an industry from antitrust liability for conduct that is voluntarily initiated."); *Image Tech. Servs. v. Eastman Kodak Co.*, 125 F.3d 1195, 1215-16 (9th Cir. 1997) (citing *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 480 n.29 (1992) ("The Supreme Court in Kodak refutes the argument that the possession by a manufacturer of "inherent power" in the market for its parts "should immunize [that manufacturer] from the antitrust laws in another market."); *Int'l Salt v. United States*, 332 U.S. 392, 395-96 (1947) (describing tying as a *per se* restraint of trade for which its patents afford no immunity from the anti-trust laws). The Ninth Circuit applies a narrow test to determine when a regulatory mandate will confer antitrust immunity:

> A regulatory mandate sufficient to confer implied antitrust immunity may in some cases exist in the presence of the following three elements: First, explicit congressional approval of the ultimate anticompetitive effect of the challenged conduct; second, explicit authorization by Congress to an agency or private entity to order the challenged anticompetitive conduct; and third, no inconsistency between the challenged conduct and an express policy of the governing agency. Such a mandate is absent here.

Phonetele, Inc. v. Am. Tel. & Tel. Co., 664 F.2d 716, 731-32 (9th Cir. 1981).

Here, there is no showing that these three requirements have been met. In addition, such a fact-intensive inquiry is inappropriate for a motion to dismiss where all facts must be construed in the light most favorable to AIDS Healthcare.

Second, adopting Gilead's position that a tying product must be currently available for sale without the need for any further regulatory approval would abrogate a significant number of tying claims where, as here, the tying product is not currently sold in a standalone form. Further, such

an unprecedented rule would contradict the consumer demand test, as it would require the court look not to the demand for a product but to the present availability of a product.

Third, the cases cited by Gilead do not support its position that regulatory approval is a bar to a tying product being a distinct product for purposes of a tying arrangement. Gilead repeatedly and unfruitfully attempts to rely on *Jefferson Parish* to buttress its argument. *Jefferson Parish* confirmed "the essential characteristic of an invalid tying arrangement lies in the seller's exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms." 466 U.S. at 12. Contrary to Gilead's arguments, the fact that there are no competitors in the marketplace does not foreclose the finding that it engaged in anti-competitive behavior. Further, in *Jefferson Parish*, the Supreme Court found that "[w]e have often found arrangements involving functionally linked products at least one of which is useless without the other to be prohibited tying devices." 466 U.S. at 19 n.30. Thus, the Court should look to the "character of demand." *See Drinkwine*, 780 F.2d at 741 (separability is "a question of character of demand"); *Digidyne*, 734 F.2d at 1339 (separability established by demand for tied product).

In *Paladin Assocs*., the Ninth Circuit affirmed a District Court's grant of summary judgment to defendants based on the plaintiff's failing to provide evidence that defendants coerced customers to purchase future transportation service on a gas pipeline. The Court did not address whether the excess gas that the defendant provided was a separate product from the alleged tied transportation service. *Paladin Assocs. v. Mont. Power Co.*, 328 F.3d 1145, 1158-59 (9th Cir. 2003). Instead, the Court found that the alleged tying claim failed as there was no proof that the "seller coerced a buyer to purchase the tied product." Therefore, this case also does not support Gilead's argument.

Contrary to Gilead's description, *Rick-Mik Enters.* does not hold that a regulatory bar to the availability of the tied product forecloses a tying claim. Instead, in *Rick-Mik Enters*., the complaint "sets forth no allegations about the franchisee market's demand for credit card services." *Rick-Mik Enters.*, 532 F.3d at 975. In contrast, here the complaint alleges a demand for TAF based on the statements of Gilead, licensing provisions, and history of products in the field.

Nor does Gilead's reliance on *Covad Commc'ns Co. v. Pac. Bell,* support its allegation that regulatory approval is a requirement of finding "two separate and distinct products." (Gilead Br. 26.) Judge Illston, in a subsequent order on a motion for reconsideration of the decision Gilead cites, clarified that the Court's dismissal of the plaintiff's claims was based on the understanding of the technology available at the time that did not indicate that voice and data services were of the nature that separate products could be sold. *Covad Communs. Co. v. Pac. Bell*, No. C 98-1887 SI, 2000 U.S. Dist. LEXIS 21267, at *15 (N.D. Cal. May 8, 2000). In contrast, AIDS Healthcare has alleged that TAF is similar to other products in the field (*e.g.*, Viread, Gilead's standalone TDF product) were separate products and that there is an ongoing demand for TAF as a standalone product.[16] In addition, the *Covad* decision was predicated on the FCC taking an affirmative position that "different service providers are not currently permitted to offer services over the same loop." *Id*. at 8-9. Unlike here, the FCC standard at the time was an affirmative bar to providers offering voice and data service offerings over the same line as separate products. In contrast, here there is no affirmative bar prohibiting the sale of TAF. The only "bar" Gilead identifies is based on the need to apply for regulatory approval of TAF. The FDA has not barred the sale of standalone TAF; rather, it simply has not yet received a request for its approval.

Gilead's reliance on *Gen. Cigar Holdings,* an out-of-Circuit case that Gilead puts forward for the proposition that there cannot be a separate tying product where the Defendants "have no power to sell their proposed tying product in the United States," is similarly unavailing. This case fails to use the requisite consumer demand test in analyzing the product markets. In addition, unlike the Cuban Cigars that were the purported tying product in *Gen. Cigar Holdings*, the TAF product is currently sold as part of combination products such as Genvoya, which include TAF along with three tied products. In *Gen. Cigar Holdings*, the sale of the tying product had not occurred (as selling Cuban cigars was illegal) and there was merely the promise of a future sale of the tying product (Cuban Cigars) once the Cuban embargo was lifted. *Gen. Cigar Holdings, Inc. v. Altadis,*

[16] Further, Judge Illston in subsequent cases confirmed the use of a four factor test in evaluating whether a combined product was in fact two products that, but for the actions of a defendant such as Gilead, would be in demand. *See Nicolosi Distrib., Inc. v. BMW of N. Am.*, 2011 U.S. Dist. LEXIS 44544, at *10 (N.D. Cal. Apr. 19, 2011) (Illston, J.).

S.A., 205 Supp. 2d 1335, 1354 (S.D. Fla. 2002). Here, TAF is being sold as part of a combined therapy that requires purchasers to also purchase other drug products (*e.g.*, cobicistat). The holding in *Gen. Cigar Holdings* thus turns not on the legal status of the tying product as a separate product, but on the fact that any sale of Cuban cigars (tied or individually) was illegal. In contrast, here there is no law or regulatory agency rule that affirmatively prohibits the sale and distribution of TAF.

B. The Complaint Pleads Facts Demonstrating Gilead's Market Power In The TAF Market

Gilead does not dispute that it is the sole maker of the foremarket product – TAF. "Gilead possesses substantial market power over the sale of TAF. For those seeking to purchase TAF, there is no other option." (FAC ¶¶ 155, 160, 178.) Gilead's claims that AIDS Healthcare has only pled market power "by inference from the existence of NCE exclusivity fails" are contradicted by the specific allegations in the complaint. (Gilead Br. 26.) The FAC's allegations are more than sufficient at the pleading stage. *See Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1052 (9th Cir. 2008) (holding that "[r]esolution of the market power question on a Rule 12(b)(6) motion is . . . inappropriate."); *Oracle Am., Inc. v. Terix Computer Co.*, No. 5:13-cv-03385-PSG, 2014 U.S. Dist. LEXIS 158060, at *13-14 (N.D. Cal. Nov. 7, 2014) ("There is no requirement that these elements of the antitrust claim be pled with specificity.").

C. The Complaint Establishes A Common Scheme And Intent To Enter Into A Conspiracy Between Gilead, Japan Tobacco, And Janssen

Gilead's claim that the "complaint lacks any allegations of fact that Defendants had a common conscious commitment to a common scheme" is contradicted by the allegations in the complaint. (Gilead Br. 27-28.) First, the complaint alleges that Gilead and Japan Tobacco agreed to jointly enforce their patents. "[Japan Tobacco] agreed to investigate any alleged or threatened infringement and assist in the investigation and enforcement." (FAC ¶ 44); *see also* Gilead Form 2015 10-K at 244-245 (Dkt. No. 35-2) (identifying that the Gilead and Janssen will work together to enforce their patent rights and provide "reasonable assistance to the Party bringing the suit or action, including providing access to relevant documents and other evidence in its possession and control."). Second, the parties entered into licensing agreements wherein Gilead "conspire[ed] with

Japan Tobacco to tie sales of TAF with elvitegravir, cobicistat, and emtricitabine, and conspire[ed] with Janssen to tie sales of TAF with rilpivirine." (FAC ¶ 142.) Third, the agreements "create and maintain unjustified monopoly profits" from the sale of combination products tying TAF to the tied products, and that Defendants Janseen and Japan Tobacco would receive "substantial payments for their part in this conspiracy." (FAC ¶ 167.) Fourth, the agreements entered into by the parties "illegally [tied] the availability of TAF to compounds such as elvitegravir and rilpivirine," in restraint of trade. (FAC ¶¶ 14, 15.) Fifth, the complaint identifies the specific agreements between Japan Tobacco, Janssen, and Gilead wherein the "parties share revenue" arising from "tying sales of TAF" to relpivirine and elvitegravir. (FAC ¶¶ 65-66, 73.)

Notably, despite the Defendants attaching the cited agreements to their motions to dismiss, they do not (and cannot) claim that the terms in the agreements contradict the allegations pled in the complaint which establish that the parties took concerted action to enter into tying agreements and share in the ill-gotten proceeds. *See* Dkt. No. 35-2 at 137 (attaching the Janssen agreement). Case law confirms that the complaint's allegations are more than sufficient, particularly at the pleading stage. *See Paladin Assocs.*, 328 F.3d 1145 (holding that intent to control prices or destroy competition is not required to prove the existence of an agreement); *In re Graphics Processing Units Antitrust Litig.,* 540 F. Supp. 2d 1085, 1096 (N.D. Cal. 2007) (citing *Oltz v. St. Peter's Cmty. Hosp.,* 861 F.2d 1440, 1450-51 (9th Cir. 1988), for the proposition that "direct evidence of concerted action in violation of the antitrust laws is rare"); *see also Standard Iron Works v. Arcelormittal,* 639 F. Supp. 2d 877, 893 (N.D. Ill. 2009) (denying motions to dismiss where "Plaintiffs have alleged no specific evidence of a conspiracy" but did allege parallel conduct and plus factors that plausibly "suggest a conspiracy"). Gilead's citation of *Monsanto Co. v. Spray-Rite Serv. Corp.*, underscores the sufficiency of the complaint. To establish the requisite "meeting of the minds" for a conspiracy, the Supreme Court in *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 768 (1984), stated:

> [T]here must be evidence that tends to exclude the possibility of independent action by the [parties]. That is, there must be direct or circumstantial evidence that reasonably tends to prove that the [parties] had a conscious commitment to a common scheme designed to achieve an unlawful objective.

Here, the intent to tie separate products together and share in the illegal proceeds is clear from the allegations concerning Defendants' agreements and conduct.

D. The Complaint Establishes An Injury To Competition And An Antitrust Injury to AIDS Healthcare

Gilead argues that AIDS Healthcare has failed to plead facts showing that competition was harmed in the market for the tied products – drugs complementary to TAF in antiretroviral medication used in HAART regimens. (Gilead Br. 16, 21.) To bring an antitrust claim and recover damages under the antitrust laws, a private plaintiff must prove the existence of "antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). "[B]ecause the Sherman Act's concern is consumer welfare, antitrust injury occurs only when the claimed injury flows from acts harmful to consumers." *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1445 (9th Cir. 1995). "Coercive activity that prevents its victims from making free choices between market alternatives is inherently destructive of competitive conditions. . . ." *Associated Gen. Contractors of Cal., Inc. v. California State Council of Carpenters ("AGC")*, 459 U.S. 519, 528 (1983). With respect to establishing its tying claim, Aids Healthcare has properly pled sufficient antitrust injury if it alleges that a "not insubstantial volume of commerce in the tied product market" is affected. *Paladin Assocs.*, 328 F.3d at 1159.[17]

AIDS Healthcare has pled that Defendants' "tying arrangement has substantially affected interstate commerce in the market for drugs complementary to antiretroviral medication used in HAART regimens." (FAC ¶ 181.) The Complaint alleges:

- "Gilead's actions have directly harmed AHF, which in 2015 alone purchased millions of dollars of HAART-related drugs from Gilead."
- "[AIDS Healthcare] is forced to purchase these tied drugs to obtain TAF." (FAC ¶ 18.)

[17] The Supreme Court's admonition in *Jefferson Parish*, that if "only a single purchaser were 'forced' with respect to the purchase of a tied item, the resultant impact on competition would not be sufficient to warrant the concern of antitrust law," *Jefferson Parish*, 466 U.S. at 16, came after a trial, not at the pleading stage. *Id.* at 5. And the Supreme Court has held that as little $60,800 was a not insubstantial volume of commerce in the tied product market. *United States v. Loew's, Inc.*, 371 U.S. 38, 49 (1962); *see also DataGate, Inc. v. Hewlett Packard Co.*, 60 F.3d 1421, 1424 (9th Cir. 1995) (sales of $100,000 per year deemed to be not insubstantial volume of commerce affected); *Tic-X-Press, Inc. v. Omni Promotions Co.*, 815 F.2d 1407, 1419 (11th Cir. 1987) ($10,091.07 not insubstantial volume of commerce affected).

- "[AIDS Healthcare] placed its first order for Genvoya on November 9, 2015." (FAC ¶ 27.)
- "[AIDS Healthcare] has placed orders for Odefsy and Descovy for its pharmacies located in California and Nevada." (FAC ¶ 28.)

In addition, the Complaint identifies other products in the tied product market that Gilead would have purchased instead of the tied products it was forced to purchase, including: Dolutegravir, Lamivudine, Raltegravir, and Darunavir. (FAC ¶ 46.) Despite Gilead's statement that "AHF's complaint never even attempts to explain how there can be injury to competition" (Gilead Br. 27), the complaint alleges: Defendants' tying arrangements caused substantial foreclosure in the relevant markets; Defendants' tying arrangements cause AIDS Healthcare to pay higher prices for products in the relevant market; Defendants' anticompetitive practices have also caused the quality of patient care to suffer as AIDS Healthcare is unable to tailor the use of TAF in HAART therapy – a particular anticompetitive harm in a health care antitrust case;[18] and Defendants' tying arrangements caused competitive distortions in the relevant markets.[19]

As the complaint lays out in detail, Gilead's gaming of the patent system and Hatch-Waxman regime has allowed it to earn profit margins in excess of 90% in 2015. (FAC ¶ 114.) The profits that Gilead earns through its exorbitant pricing of branded pharmaceuticals is paid predominantly by state and local governments through the collection of taxes. Thus, Gilead's 50 billion dollars in profits (roughly equivalent to those of Microsoft during the same period) are a direct transfer from the pockets of the American taxpayers to the executives and shareholders of Gilead.

Contrary to Defendants' contention, the law does not require a plaintiff to specifically identify foreclosed competitors to demonstrate anticompetitive effects. *See Datagate, Inc. v. Hewlett-Packard Co.*, 941 F.2d 864, 870 (9th Cir. 1991) (reversing dismissal of tying claim and finding that allegations of forcing alone were sufficient to show significant impact on competition).

[18] *See, e.g., New York Medscan, LLC v. NYU Sch. of Med.*, 430 F. Supp. 2d 140, 148 (S.D.N.Y. 2006) (denying motion to dismiss in antitrust case when "the quality of diagnostic imaging services purportedly has decreased" due to the alleged restraints).

[19] *See Rick-Mik*, 532 F.3d at 971 (The injury created by a tying arrangement "is reduced competition in the market for the tied product.").

Given the anticompetitive effects of Defendants' tying arrangements, the complaint provides a multipronged enunciation of injury to competition.

E. Defendants' Other Defenses Fail

Gilead also contends that its patent rights immunize its conduct and that AIDS Healthcare is improperly attempting to impose an affirmative duty on Gilead to aid competitors. Neither argument is correct.

1. AIDS Healthcare's Claims Do Not Stem From Any Failure By Gilead To Aid Competitors

As to Gilead's claim that AIDS Healthcare is demanding that Gilead aid a competitor, the complaint makes clear that AIDS Healthcare complains only of Gilead's affirmative acts. The complaint primarily attacks the effect of the tying agreements between Gilead, Japan Tobacco, and Janssen in tying the sale of TAF to other drugs. In addition, the cases Gilead cites that hold that a monopolist has "no duty to aid competitors" or to "share the source of [its] advantage" are Sherman Act Section 2 cases, not Section 1 cases. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407–08 (2004). They establish only that a monopolist has no duty to aid its competitors; however, a monopolist violates Section 1 of the Sherman Act when it makes agreements with other entities that restrain trade or commerce and injure competition.

Gilead cites *United States v. Westinghouse Electric Corporation*, 648 F.2d 642, 647 (9th Cir. 1981), for the proposition that the antitrust laws do not require an alleged dominant company to compete against itself by licensing its intellectual property to other firms. (Gilead Br. 24.) But AIDS Healthcare only seeks to prevent Gilead from entering into illegal agreements to tie TAF to other compounds made by Gilead's licensing partners. *See Westinghouse*, 648 F.2d at 647 ("Of course, a patent holder may run afoul of the antitrust laws.").[20]

Gilead's reliance on *Genetech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 949 (Fed. Cir. 1993), is also misplaced. Gilead cites this case for the proposition that a patentee has the right to select its

[20] *Westinghouse* was not a case about standing or pleading standards. Instead, in *Westinghouse*, the Ninth Circuit was reviewing a full trial record that took place after six years of discovery that concluded with a bench trial resulting in a verdict in favor of the defendants. *Westinghouse*, 648 F.2d at 645. The correctness of a verdict reached after years of discovery and witness testimony has no bearing on whether a pleading should be dismissed before any opportunity for the very factual development that *Westinghouse* relied upon could be had.

own licensees. (Gilead Br. 24.) However, the opinion goes on to explain that the dismissal was based on the threadbare allegations in the complaint. "Genentech's pleading does not allege more substance than the University's grant of an exclusive license to Lilly." *Id*. at 949. In contrast, here the complaint alleges not merely patent licensing but a concerted effort to tie the sales of TAF to other products and profit through these agreements. In addition, the complaint identifies that these unlawful tying agreements between Defendants were significantly more than a patent license, it was a scheme where "power gained through some natural and legal advantage such as a patent, copyright, or business acumen" "exploits his dominant position in one market to expand his empire into the next." *Eastman Kodak*, 504 U.S. at 479 n.29 (citation omitted). These sorts of activities "give rise to liability." *Id.*

2. Defendants' Tying Arrangement Should, At A Minimum, Be Subject To Rule Of Reason Analysis

Gilead claims that it is immune from antitrust liability as its TAF-containing products are an improvement and thus fit within "a line of product innovation cases" that "reject[] antitrust liability for a monopolist's decision about when or whether to market new products." (Gilead Br. 16.) The doctrine cited by Gilead is inapplicable for three reasons. *First*, that doctrine does not extend to immunize Gilead from AIDS Healthcare's Section 1 and 2 claims, which do not merely allege that Gilead has released a product with anticompetitive features. AIDS Healthcare's claims under both Section 1 and 2 allege that it is Gilead's affirmative act of entering into tying agreements with Japan Tobacco and Janssen that evidence the parties' use of Gilead's monopoly power in the TAF market to leverage access in other markets. Even the cases cited by Gilead recognize that "product innovation" does not immunize antitrust liability where a party introduces a new product (TAF) and enters into agreements with third parties that enable the party to tie the purchase of the new product to other products. *See Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 998 (9th Cir. 2010) ("changes in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly under Section 2").

Second, Gilead mischaracterizes AIDS Healthcare's claims. AIDS Healthcare has not made a predatory pricing claim or a refusal to deal claim. AIDS Healthcare does not ask or expect Gilead to assist it, or to share a product with it, and AIDS Healthcare's allegations are far different from what Gilead argues. AIDS Healthcare's claims are about the anticompetitive agreements which Gilead had entered into with Japan Tobacco and Janssen, agreements in restraint of trade that foreclose competitor access to the aftermarket for drugs complementary to antiretroviral medication used in HAART regimens. These agreements harm customers and harm competition.

Third, the cases relied on by defendants are either distinguishable or support a finding of antitrust liability based on a second act such as tying. Gilead's reliance on refusal to deal cases such as *Oahu Gas Serv., Inc. v. Pac. Res. Inc.*, 838 F.2d 360, 369 (9th Cir. 1988), and *Goldwasser v. Ameritech Corp.*, 222 F. 3d 390, 397 (7th Cir. 2000), is ineffective. (Gilead Br. 16-17.) It is the unique "price disconnect" in the marketplace and the ability of a drug company such as Gilead to "game" the Hatch-Waxman system that these cases do not address. Gilead's attempt to cast itself as a monopolist who is simply "entitled to compete" or is increasing competition through purported product improvement is something it can argue to the jury.

Similarly, Gilead's reliance on *Allied Orthopedic*, 592 F.3d 991, misses the mark. That case involved a pulse oximetry machine and the single-use sensors that the machine used to monitor oxygen levels in medical patients. There, the defendant's redesigned monitoring machine was no longer compatible with generic sensors. But in that case, the "incompatibility" of the competitors' generic sensors with the newly redesigned monitoring system "was the necessary consequence" of the design improvements themselves—the improvements could not have been accomplished otherwise. *Id*. at 1002 (emphasis added). Here, the complaint pleads that Gilead's entering into agreements with Japan Tobacco and Janssen to only introduce combination drugs containing TAF in lieu of a standalone version of TAF is ample evidence demonstrating precisely the opposite.

Gilead also mistakenly relies on two telecommunications cases arising under the Federal Communications Act — *Trinko* and *Pac. Bell Tel. v. Linkline Commc'ns., Inc.*, 555 U.S. 438, 454 (2009)—to argue it cannot be required to deal with its competitors. Neither decision aids Gilead. This case is nothing like *Trinko* or *Linkline* because AIDS Healthcare did not seek to be engaged

in any commercial relationship with Gilead. The Supreme Court observed in *Trinko* that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry in question."

3. AIDS Healthcare Pleads Facts Establishing Anti-Competitive Tying Restrictions Between Gilead, Japan Tobacco, and Janssen

Japan Tobacco claims that an exclusive licensee "is legally incapable of conspiring with an exclusive licensee to violate the antitrust laws." (Dkt. No. 80 ("Japan Tobacco Br.") 1.) Japan Tobacco's reliance on *Levi Case Co., Inc. v. ATS Prods., Inc.*, 788 F. Supp. 428, 431-32 (N.D. Cal. 1992), in support of this purported legal dictum is misplaced and incorrect. The court in *Levi Case*, on summary judgment (as opposed to the posture of Japan Tobacco's motion to dismiss) applied the "single entity" rule to an arrangement where the exclusive licensee and patent owner had identical interests and thus were functionally a "single entity." Subsequent decisions have pointed out the narrow nature of the Order in *Levi Case*. *See e.g., Pecover v. Elec. Arts Inc.*, 633 F. Supp. 2d 976, 984 (N.D. Cal. 2009) ("[The] *Levi Case* is distinguishable from the instant complaint . . . . A series of agreements between EA and each of these entities could plausibly deprive the marketplace of independent sources of economic power."); *Townshend v. Rockwell Int'l Corp.*, 2000 U.S. Dist. LEXIS 5070, at *16-17 (N.D. Cal. Mar. 28, 2000) ("While the facts in *Levi Case* resulted in a finding by that court that a patent holder and its exclusive licensee were incapable of entering into a conspiracy with respect to their conduct with sublicenses, ***the court did not set forth a bright-line rule that patent holders and their licensees could never conspire***. In fact, the *Levi Case* court explained that the relationship between a patent holder and its licensee could be a conspiracy in violation of the antitrust laws if the relationship "deprived the marketplace of independent actors.") (emphasis added). Here, AIDS Healthcare has alleged a series of agreements (*e.g.*, Japan Tobacco-Gilead Agreement) that, through tying TAF to aftermarket drugs deprive the marketplace of independent actors. (FAC ¶¶ 17, 145, 199.)

Japan Tobacco also relies on this Court's ruling in *Apple, Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1195 (N.D. Cal. 2008), where this Court found that the Apple operating system (iOS) and Apple Computer Hardware were not distinct products. Despite Japan Tobacco's claim that the market

for TAF is "not supported by any factual allegations" and "this Court has rejected allegations that an antitrust market can consist of just one single brand" (Japan Tobacco Br. 5), the holding in *Apple, Inc*. was significantly more narrow. For example, this Court found that the antitrust claimant in *Apple, Inc.*, failed to plead a plausible aftermarket for Apple Hardware because customers "knowingly agree to the challenged restraint." *Id*. at 1200-02. In addition, *Psystar* failed to allege facts supporting a claim that the foremarket in Apple's operating system was "so unique" that it "suffers no actual or potential competitors." *Id*. at 1198. Here, AIDS Healthcare's complaint alleges multiple bases for the uniqueness and distinct contours of the TAF market.

Janssen's motion to dismiss is also largely duplicative of Gilead's motion. AIDS Healthcare incorporates its responsive arguments. For example, Janssen claims that AIDS Healthcare fails to allege facts establishing "Janssen intended to restrain trade by entering a license agreement with Gilead." (Dkt. No. 83 ("Janssen Br.") 5.) However, the complaint not only identifies the specific anticompetitive agreement between Gilead and Janssen (FAC ¶ 73), the complaint identifies the provisions in the agreement that tie the sale of TAF to Janssen's rilpivirine product. (*Id*. ¶ 142 ("tie sales of TAF with rilpivirine in an effort to obtain and share monopoly profits on the sale of TAF")). As discussed *supra* Part VI, these allegations are sufficient to establish AIDS Healthcare's claims for violation of Section 1 of the Sherman Act.

VII. AIDS HEALTHCARE HAS STATED A CLAIM FOR MONOPOLIZATION, AND ALTERNATIVELY, ATTEMPTED MONOPOLIZATION UNDER SHERMAN ACT § 2

"The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Eastman Kodak*, 504 U.S. at 481. To establish a tying claim, a plaintiff must show "(1) that there exist two distinct products or services in different markets whose sales are tied together; (2) that the seller possesses appreciable economic power in the tying product market sufficient to coerce acceptance of the tied product; and (3) that the tying arrangement affects a 'not insubstantial volume of commerce' in the tied product market. *Paladin Assocs.*, 328 F.3d at 1159 (quoting *Eastman Kodak*, 504 U.S. at 461-62).

Gilead uses its monopoly power in the TAF market in an attempt to monopolize the aftermarket for drugs that are used in combination with TAF for HAART therapies. Gilead argues that there is no viable foremarket in TAF because standalone TAF is not FDA approved. (Gilead Br. 15.) This argument fails on multiple levels as discussed *supra* in Part VI.A.2. The complaint alleges that Gilead not only possesses a monopoly in the foremarket for TAF, but is also seeking to monopolize the aftermarket in drugs that are used in combination with TAF for HAART therapies.

In any antitrust case requiring market definition, the relevant market consists of "any grouping of sales whose sellers, if unified by a monopolist or a hypothetical cartel, would have market power in dealing with any group of buyers." *Rebel Oil*, 51 F.3d at 1434. Market power, in turn, is the ability of a firm or firms to increase their profits by restricting output or charging more than a competitive price. *Id.* As applied, the question is whether a firm with a monopoly share of the foremarket could earn greater profits by charging above competitive levels by conditioning the purchase of the foremarket product on another product. Here, Gilead requires purchasers of TAF to acquire other (non-TAF) drug products as part of Gilead's fixed dose combination tablets.

The complaint alleges that Gilead knew that, by "combining TAF with elvitegravir, cobicistat, and emtricitabine, it would" be able to use its monopoly power in TAF to extend its market power in aftermarket drugs. (FAC ¶ 158.) Further, Gilead knew and intended to deter potential market entrants by creating expensive and time-consuming barriers to entry resulting from the tying of TAF to elvitegravir, cobicistat, emtricitabine, and rilpivirine specifically to create and maintain monopoly profits on the sale of TAF. (*Id*.) The cases upon which Gilead relies in seeking dismissal of AIDS Healthcare's Section 2 claim are all cases in which the foremarket was competitive and consumers were able to make a knowing decision in a competitive market about whether to agree in advance to aftermarket restrictions. While foremarket power is not *required* for a Section 2 monopolization claim (*see Eastman Kodak*, 504 U.S. 451 (1992)), a defendant with market power in a foremarket cannot abuse that power to gain an additional monopoly in a collateral market.

In its complaint, AIDS Healthcare alleges both a relevant product foremarket consisting of TAF and that Gilead had market power in this market. (FAC ¶¶ 3, 13, 118-27, 142.) AIDS Healthcare further alleges that regulatory barriers to entry mean that Gilead enjoys market power in the market for TAF. (*Id.*) Assuming these allegations are true, as they must be at this stage of the proceedings, consumers do not agree to purchase the non-TAF drugs in the fixed dose combination therapies sold by Gilead.

VIII. THE COMPLAINT PROPERLY STATES A CLAIM UNDER § 17200

California Business and Professions Code § 17200 ("UCL") proscribes any "unfair competition" that includes "unlawful, unfair or fraudulent business act or practice." *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999) (quoting Cal. Bus. & Prof. Code § 17200). AIDS Healthcare sufficiently pleads at least three separate, distinct violations of California's UCL – at least two claims as to all Defendants and a third that is specific to Gilead.

A. Defendants' Tying Conduct Violates Antitrust Law, Thus Violating § 17200's "Unlawful" Prong

As discussed above, AIDS Healthcare adequately pleads a violation of Sections 1 and 2 of the Sherman Act for Gilead and all Defendants' actions in tying the sale of other HAART therapy drugs to the sale of TAF. By sufficiently pleading allegations that this conduct was unlawful under federal and state antitrust laws, AIDS Healthcare has adequately pled a claim under the "unlawful" prong of California's UCL. "When determining whether a practice is 'unlawful,' section 17200 'borrows' violations of other laws . . . ." *AICCO, Inc. v. Ins. Co. of N. Am.*, 90 Cal. App. 4th 579, 587 (Cal. App. 2001). "Virtually any law—federal, state or local—can serve as a predicate for a section 17200 claim." *Id.* (citing *Stevens v. Superior Court*, 75 Cal. App. 4th 594, 602 (Cal. App. 1999)).

Gilead argues that AIDS Healthcare's UCL claim should be dismissed because its antitrust claims are subject to dismissal. As discussed above, the premise of Gilead's argument is incorrect; AIDS Healthcare adequately pleads federal and state law antitrust claims. However, even assuming, *arguendo*, that the antitrust claims were dismissed, California's UCL is not so limited. As the California Supreme Court has held, it encompasses "conduct that threatens an incipient violation of an antitrust law, or violates the policy or spirit of one of those laws because its effects

are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition." *Cel-Tech*, 20 Cal. 4th at 187. Defendants' product-tying conduct is a plain violation of the antitrust law. But at a minimum, it violates the "policy or spirit" of antitrust law.

B. Defendants' Attempt To Game FDA Law And Extend The Length Of Gilead's Monopoly Over TAF Violates § 17200's "Unfair" Prong

AIDS Healthcare's complaint alleges that Defendants have conspired to release TAF products only in combination with other HAART drugs in an effort to prolong Gilead's monopoly over TAF by insulating the weak patents covering TAF Paragraph IV challenges arising from a generic competitor's Abbreviated New Drug Application ("ANDA"). (FAC ¶¶ 11-14, 104-09, 115, 190-92.) These allegations sufficiently state a violation of California's UCL under the "unfair" prong.

In attacking AIDS Healthcare's UCL claim, Gilead argues that there is not "constitutional, legislative, or regulatory policy" tethered to Gilead's allegedly unlawful conduct. (Gilead Br. 29.) Gilead is wrong. The purpose of the Hatch-Waxman Act is to make it "easier for drug manufacturers to obtain approval for generic drugs" by not requiring a generic manufacturer to "undertake the complicated and time consuming testing process associated with an NDA . . . ." *Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 579 (D.C. Cir. 2001). Specifically, with respect to 505(b)(2) applications, Congress recognized the significant investment required by new clinical investigations and rewarded successful 505(b)(2) applicants utilizing "new clinical investigations" with three years of exclusivity as to that indication. 21 U.S.C. § 355(c)(3)(E)(iii).

Defendant Gilead argues that AIDS Healthcare fails to state a claim under § 17200 because a generic manufacturer can submit a "505(b)(2)" application for standalone TAF. (Gilead Br. 19 (citing 21 U.S.C. § 355(b)(2)).) However, Gilead dramatically oversimplifies the analysis. A potential competitor mulling the decision to enter the market with a standalone TAF product is faced with the realities of Gilead's gamesmanship of FDA law. Because of the NCE exclusivity Gilead repeatedly touts, a potential market entrant is prohibited from filing a 505(b)(2) application until at least November 5, 2019. (Gilead Br. 5 (citing 21 C.F.R. § 314.108(b)(2)).) Because Gilead has, as of now, not sought FDA approval of standalone TAF indicated for the treatment of HIV, a potential competitor would need to conduct clinical investigations establishing the effectiveness of

a standalone TAF product for the treatment of HIV. *See* 21 U.S.C. § 355(b)(1)-(2). Therefore, a potential market entrant faces the reality of investing years and millions of dollars to conduct additional clinical trials knowing full well that Gilead can (and likely will) wait until the tail end of its current NCE exclusivity to conduct the same trials and release its own standalone TAF product before anyone potential competitor can file a 505(b)(2) application.

Defendants' actions here undermine the Hatch-Waxman Act's regulatory scheme designed to incentivize consumer access to affordable drugs. Had Gilead released a standalone TAF product, the path to regulatory approval by a potential generic entrant would have been straightforward: it could have waited until November 5, 2019, and filed an ANDA that included a challenge to just the weak TAF patents without expending the significant resources on clinical trials required of 505(b)(2) applicants. In fact, if the market entrant was the first-to-file ANDA applicant, it would be entitled to the additional incentive of 180 days as the only generic competitor to Gilead's standalone TAF. *See* 21 U.S.C. § 355(j)(5)(B)(iv). However, by not releasing standalone TAF and shielding TAF's comparatively weak patents by tying the release of TAF with other HAART drugs with much stronger patents, Defendants have forced potential market entrants into a daunting situation.

Gilead's clever gamesmanship of FDA law disincentivizes a potential entrant to the TAF market from pursuing a 505(b)(2) application for several reasons. First, the resources required for clinical trials would be wasted because Gilead would likely pursue standalone TAF by the end of its current NCE exclusivity. Second, not only could Gilead undercut a potential market entrant's contemplated 505(b)(2) application, but Gilead could then receive three years of additional exclusivity over the standalone TAF product. 21 U.S.C. § 355(c)(3)(E)(iii). Third, once Gilead's additional three-year exclusivity on standalone TAF indicated for the treatment of HIV came to a close, other generic competitors would be incentivized to file ANDA applications pursuant to section 505(j) because the first-filer would obtain a 180-day period during which it would be the only ANDA approved by the FDA, thus allowing it to reap the profits of limited competition. 21 U.S.C. § 355(j)(5)(B)(iv).

Accordingly, a potential market entrant seeking to sell standalone TAF must either (1) challenge all the patents covering all drug products contained in either Genvoy, Odefsey, and/or Descovy in an ANDA, which is difficult given the relative strength of the patents covering the non-TAF (tied) drugs, or (2) wait until Gilead releases a standalone TAF product at the tail end of its current NCE exclusivity period, then wait an additional three-year period of exclusivity that is probable for the standalone version, and only then file an ANDA challenging the TAF patents. Thus, through nothing other than Defendants' gamesmanship and product tying, Gilead is likely to maintain its monopoly over TAF for 3-4 years beyond what the Hatch-Waxman regime intended.

Gilead argues that the "tethering test" applies to AIDS Healthcare's UCL claim. (Gilead Br. 29.) Under the "tethering test," "unfairness must 'be tethered to some legislatively declared policy or proof of some actual or threatened impact on competition.'" *Lozano v. AT&T Wireless Servs.*, 504 F.3d 718, 735 (9th Cir. 2007) (quoting *Cel-Tech*, 20 Cal. 4th at 186-187). "[A] practice may be deemed unfair even if not specifically proscribed by some other law." *Cel-Tech*, 20 Cal. 4th at 180. As discussed above, even under the "tethering test," AIDS Healthcare has stated a claim because Defendants' actions undermine the purposes of the Hatch-Waxman Act.

It is unclear, however, whether the "tethering test" or the "balancing test" applies here. "While California appellate courts are not completely settled on what constitutes an 'unfair' business practice, unfairness is generally determined by either the 'balancing test' or the 'tethering test.'" *Guttmann v. Nissin Foods (U.S.A.) Co.*, 2015 U.S. Dist. LEXIS 92756, at *9 (N.D. Cal. July 15, 2015) (Alsup, J.) (citing *Lozano*, 504 F.3d at 736). "[T]he balancing test 'involves balancing the harm to the consumer against the utility of the defendant's practice.'" *Guttmann*, 2015 U.S. Dist. LEXIS 92756, at *9-10 (quoting *Lozano*, 504 F.3d at 735). In *Guttmann*, this Court held that the plaintiff plausibly alleged a violation of the UCL under the balancing test because the complaint alleged "in great detail the serious harm artificial trans-fat poses to public health" and that "the only utility in the use of partially-hydrogenated oils, as opposed to oils that do not contain artificial trans-fat, is that partially-hydrogenated oils are less expensive." *Guttmann*, 2015 U.S. Dist. LEXIS 92756, at *10. Here, AIDS Healthcare has extensively pled the harms to end-user consumers, including facing the choice of using either (1) vastly inferior and dangerous TDF in a standalone

form, or (2) making do with Gilead's paternalistic limiting of treatment options through the three fixed-dosage combination options incorporating TAF (i.e., Genvoya, Odefsey, and Descovy). Further, Defendants' tying conduct subjects both end-user patients and purchasers of TAF-containing products such as AIDS Healthcare to exorbitant, monopoly costs of TAF for years beyond the time at which generic competition would normally be expected to enter the market.

Defendants identify no utility to their practice of releasing TAF only tied to other HAART drugs. Defendant Gilead simply mischaracterizes FDA Guidance, arguing that the FDA has sought to encourage Defendants' tying conduct. (Gilead Br. 29.) Gilead is again wrong. By cherry-picking and mischaracterizing FDA guidance documents, Gilead attempts to mislead the Court into believing that the FDA has encouraged Gilead's tying practices. The FDA has not sought to encourage the release of combination drugs *in lieu of* standalone versions of a combination drug's constituent parts. For example, Gilead states that "the FDA actively encouraged innovators to seek approval of new drugs as part of combinations *without first obtaining standalone approval*." (Gilead Br. 29. (emphasis in original).) However, Gilead conveniently glosses over the very title of that FDA guidance, which applies only to "*Certain* Fixed-Combination Drug Products." (Dkt. No. 81-2 at 2 (Ex. A to Gilead Br.) (FDA Guidance for Industry, *New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products* (Oct. 2014)) (emphasis added).)

Further, Gilead omits from its discussion that the FDA guidance cited in its brief was issued in response to Gilead's own Citizen Petition to the FDA (Berger Decl. Ex. F). (*See* Dkt. 81-2 at 7 n.29 (noting that the first request for the FDA to revise its 5-year NCE interpretation came on behalf of Gilead Sciences, Inc.).) In that Citizen Petition, Gilead requested that the FDA grant NCE exclusivity on any new active moiety contained in a fixed dose combination (FDC) drug. Berger Decl. Ex. F at 1. The Citizen Petition did not request that the FDA approve or encourage drug makers to seek approval of combination drugs to the exclusion of standalone drugs. In fact, Gilead assured the FDA that the two new active moieties addressed in its Citizen Petition were being developed "separately as single entity drug products." *Id.* at 12 (explaining that EVG and COBI were the subject of single entity product New Drug Applications pending before the FDA).

In the FDA's guidance cited in Gilead's Brief, the FDA states that it "has encouraged the development of [combination] therapies through various policies and initiatives," citing its recently-finalized "guidance for industry titled *Codevelopment of Two or More New Investigational Drugs for Use in Combination* (Codevelopment Guidance)."[21] (Dkt. No. 81-2 at 2.) Gilead conveniently fails to address the FDA's Codevelopment Guidance, which is unsurprising given that the Codevelopment Guidance undermines Gilead's argument that the FDA has sought to encourage combination drugs in lieu of standalone drug products. For example, the Codevelopment Guidance states:

> Because co-development generally will provide less information about the individual new investigational drugs, it may present greater risk compared to clinical development of an individual drug. Given this concern, FDA believes that codevelopment should ordinarily be reserved for situations that meet all of the following criteria: [The Guidance then lists four lengthy, fact-specific factors omitted here]. ***FDA recommends that sponsors consult with FDA on the appropriateness of codevelopment before initiation of clinical development of a combination***.

Codevelopment Guidance, Berger Decl. Ex. G at 2-3 (emphasis added).

Gilead does not argue in its brief that it consulted with the FDA regarding its codevelopment of Genvoy, Odefesy, or Desocvy, nor does Gilead argue that any of these three products satisfy the FDA's highly fact-specific inquiry as to whether a drug is appropriate for codevelopment rather than development as individual drugs.

While the FDA has adopted certain policies and guidance that permit codevelopment of drugs *in appropriate circumstances*, the FDA has not broadly and indiscriminately decided to "encourage" any and all codevelopment strategies. The FDA certainly has not promulgated any rule or regulation that would provide a "safe harbor" immunizing Gilead under California's UCL. "[A] plaintiff may not bring an action under the unfair competition law if some other provision bars it. That other provision must actually bar it, however, and not merely fail to allow it." *Cel-Tech*, 20 Cal. 4th at 182. "[T]he Legislature's mere failure to prohibit an activity does not prevent a court

[21] AIDS Healthcare respectfully requests that the Court take judicial notice of FDA Guidance for Industry, *Codevelopment of Two or More New Investigational Drugs for Use in Combination*, available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm236669.pdf, and attached to the Berger Decl. as Ex. G.

from finding it unfair." *Id.* Here, the FDA guidance Gilead points to merely stands for the proposition that the FDA will not penalize the developer of a combination therapy by refusing NCE exclusivity for a new active moiety within that combination therapy. Nothing in the FDA's guidance establishes that the FDA intends to encourage or immunize developers from seeking approval of combination therapies in lieu of individual drugs. Accordingly, no safe harbor shields Defendants' actions from a § 17200 claims. *See, e.g., Guttmann*, 2015 U.S. Dist. LEXIS 92756, at *11-12 ("The FDA's prior declination to issue a regulation pertaining to all artificial trans-fats did not establish a safe harbor protecting use of that ingredient from the reach of California law.").

C. Gilead's Delay In Developing TAF In An Effort To To Extend Its Monopoly Profits Violates § 17200's "Unfair" Prong

Solely focused on maintaining its high revenue and profits, Gilead intentionally stalled on the development of TAF despite recognizing the superiority of TAF over TDF. (FAC ¶¶ 8, 53-59.) Gilead went so far as to publicly announce that it was discontinuing the development TAF while simultaneously filing seven patent applications relating to the use of TAF to treat HIV. (*Id.* at ¶¶ 57-58.) Tellingly, it took Gilead only approximately three years from filing its first patent relating to TDF until receiving FDA approval of the first TDF product while it took Gilead approximately 15 years from first filing a patent application relating to TAF until the first TAF-containing product was approved by the FDA. (FAC ¶¶ 8-11, 23, 58, 99-101.) Despite the knowledge of TAF's superiority over TDF, Gilead undertook a misleading campaign in an effort to delay the release of TAF until just before the entry of generic competition in the TDF market. Under either the "tethering test" or the "balancing test," AIDS Healthcare has properly pled that Gilead's actions violate § 17200's "unfair" prong.

The very FDA guidance cited in Gilead's brief establishes the legislative policy to which Gilead's unfair business practices are tethered.

> In addition to establishing the drug approval pathways in section 505(b)(2) and (j) of the FD&C Act, the Hatch-Waxman Amendments authorized periods of exclusivity *intended to provide incentives for pharmaceutical innovation* by protecting certain drugs approved in an NDA from competition for certain periods.

(Dkt. No. 81-2 (FDA Guidance) at 3 (emphasis added).)

The FDA guidance on which Gilead relies in its brief changed the FDA's interpretation of how it awards the 5-year NCE exclusivity based upon citizen petitioning from, among others, Gilead. (*Id.* at 7 n.29.) In explaining the change in how it will award 5-year NCE exclusivities, the FDA explained that it wanted to avoid gamesmanship from drug companies and to expedite the release of needed drugs:

> [T]he petitioners [who include Gilead] stated that FDA's historical interpretation might encourage an applicant to submit an NDA for a single-entity product before it submits an NDA for a fixed-combination to secure 5-year NCE exclusivity for the single entity and protect the later-approved fixed-combination with that exclusivity under the umbrella policy. *This might lead to suboptimal drug development strategies*, especially in light of the increasing importance of fixed-combinations. In addition, the petitioners stressed that timing the order of approval to preserve exclusivity may not be available in some situations, such as for a new active moiety that may not be effective or safe unless it is marketed in a fixed-combination.
>
> In light of the increasing importance of fixed-combination products to treat serious diseases and conditions, and considering the factors discussed above, *FDA has concluded that a new interpretation of 5-year NCE exclusivity for fixed-combination products would be beneficial to the public health*.

(*Id.* at 7-8 (emphasis added).)

In Gilead's Citizen Petition, Gilead extensively laid out the Hatch-Waxman Act's "incentive structure designed to authorize affordable generic drugs without undermining the development of innovative drugs." Berger Decl. Ex. F at 3-5.

Had Gilead pursued TAF upon first learning of its therapeutic superiority to TDF, Gilead would have displaced TDF and eliminated several years of monopoly profits. Instead, Gilead waited until the eve of generic competition in the TDF market then "product hopped" to TAF, thus eliminating much of the demand for TDF (including generic TDF) and began a new 5-year exclusivity period during which it can continue to enjoy monopoly profits. Gilead's conduct undermines the legislative purpose of the Hatch-Waxman Act. The purpose of the 5-year exclusivity period is to incentivize drug developers to invest in and release innovative products. Gilead used the promise of a 5-year exclusivity on TAF to delay by several years the release of a drug critical to public health and to marginalize the threat of generic competition (the other purpose of the Hatch-Waxman Act). Because Gilead's conduct is both unfair and "tethered to some legislatively declared policy or proof of some actual or threatened impact on competition,'" it violates California's UCL. *Lozano*, 504 F.3d at 735 (quoting *Cel-Tech*, 20 Cal. 4th at 186-187).

Turning to the "balancing test," Gilead does not identify any utility to gaming FDA law in an effort to ensure it reaps the full benefit of its monopoly on TDF by delaying the release of a far safer product (TAF). In reality, the only utility in Gilead's course of conduct is to maximize Gilead's profit. To avoid dismissal of a § 17200 claim under the "balancing test," AIDS Healthcare need only show that it "could prove facts showing that the harm was not outweighed by the utility." *Lozano*, 504 F.3d at 736. AIDS Healthcare has pled that patients suffered with higher bone and kidney toxicities from TDF for nearly a decade due to Gilead's actions. (FAC ¶ 8.) AIDS Healthcare has also pled that purchasers, including AIDS Healthcare have been injured economically because they paid monopoly prices for an inferior product and will now continue to pay monopoly prices for TAF for years to come. (FAC ¶¶ 79, 108, 118-19, 124-31.) These harms are not outweighed Gilead's interest in profit maximization.

IX. THE COMPLAINT PROPERLY STATES A CLAIM UNDER THE CARTWRIGHT ACT AND UNDER NEVADA LAW

AIDS Healthcare brings claims under California's Cartwright Act and under the Nevada Unfair Trade Practices Act ("Nevada UTP") for damages arising from Defendants' anticompetitive actions alleged in the Sherman Act claims above. Defendants have waived, for the purposes of the pleadings stage, any argument that AIDS Healthcare lacks standing under the Supreme Court's *Illinois Brick v. Illinois*, 431 U.S. 720 (1977), decision.[22] AIDS Healthcare believes this waiver is appropriate as the facts of this case fit within the "control exception" to the extent *Illinois Brick* applies. However, to the extent Defendants raise *Illinois Brick* at a later stage of the case, both California's Cartwright Act and Nevada's UTP allow indirect purchaser plaintiffs to maintain antitrust actions modeled on the Sherman Act. *Lorenzo v. Qualcomm Inc.*, 603 F. Supp. 2d 1291, 1302 (S.D. Cal. 2009) ("The Cartwright Act 'is patterned after the federal Sherman Anti-Trust Act . . . . However, standing under California's Cartwright Act is broader than standing under the Sherman Act insofar as the Cartwright Act explicitly permits indirect purchasers to bring suits for damages and injunctive relief . . . ."") (citations omitted); *In re Static Random Access Memory Antitrust Litig.*, Case No. 07-md-01819 CW, 2010 U.S. Dist. LEXIS 131002, at *40 (N.D. Cal.

[22] Berger Decl. Ex. J.

Dec. 8, 2010) (Nevada unfair trade practices law is "construed in harmony with prevailing judicial interpretations of the federal antitrust statutes" except that "any 'person injured or damaged directly or indirectly' . . . may bring suit.") (citations omitted). Additionally, as AIDS Healthcare addresses in detail above, it has suffered an antitrust injury, and thus has standing to bring its Sherman Act claims. However, Nevada's UTP law does not require a plaintiff to satisfy the antitrust injury standing standard promulgated in *AGC*, 459 U.S. 519. *In re Flash Memory Antitrust Litig.*, 643 F. Supp. 2d 1133, 1151 (N.D. Cal. 2009).

X. CONCLUSION

For all the foregoing reasons, this Court should deny all of the proffered grounds for dismissal in Defendants' motions.[23]

[23] In the alternative, should the Court grant Defendants' motions in whole or in part, AIDS Healthcare respectfully requests leave to amend. *See Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051–52 (9th Cir. 2003) (holding that "leave [to amend a pleading] shall be freely given when justice so requires . . . [and] [t]his policy is to be applied with extreme liberality" and stating that "there exists a *presumption* . . . in favor of granting leave to amend") (internal quotation marks omitted).

Dated: May 31, 2016

Respectfully submitted,

/s/ Daniel P. Hipskind
Dorian S. Berger CA Bar No. 264424
Daniel P. Hipskind CA Bar No. 266763
BERGER & HIPSKIND LLP
1880 Century Park East, Ste. 815
Los Angeles, CA 90067
Telephone: 323-886-3430
Facsimile: 323-978-5508
E-mail: dsb@bergerhipskind.com
E-mail: dph@bergerhipskind.com

Tom Myers, CA Bar No. 176008
Arti L. Bhimani, CA Bar No. 235240
Liza M. Brereton, CA Bar No. 261380
AIDS HEALTHCARE FOUNDATION
6255 W. Sunset Blvd., 21st Fl.
Los Angeles, California 90028
Telephone: 323-860-5200
Facsimile: 323-467-8450
Email: Tom.Myers@aidshealth.org
Email: Arti.Bhimani@aidshealth.org
Email: Liza.Brereton@aidshealth.org

Attorneys for Plaintiff AIDS Healthcare Foundation, Inc.